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Treatment for ulnar neuropathy at the elbow.

*Cochrane Database of Systematic Reviews* 2016, Issue 11. Art. No.: CD006839.

DOI: 10.1002/14651858.CD006839.pub4.

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# Treatment for ulnar neuropathy at the elbow

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**Editorial group:** Cochrane Neuromuscular Group.

**Publication status and date:** New search for studies and content updated (conclusions changed), published in Issue 11, 2016.

**Citation:** Caliendo P, La Torre G, Padua R, Giannini F, Padua L. Treatment for ulnar neuropathy at the elbow. *Cochrane Database of Systematic Reviews* 2016, Issue 11. Art. No.: CD006839. DOI: 10.1002/14651858.CD006839.pub4.

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## ABSTRACT

### Background

Ulnar neuropathy at the elbow (UNE) is the second most common entrapment neuropathy after carpal tunnel syndrome. Treatment may be conservative or surgical, but optimal management remains controversial. This is an update of a review first published in 2010 and previously updated in 2012.

### Objectives

To determine the effectiveness and safety of conservative and surgical treatment in ulnar neuropathy at the elbow (UNE). We intended to test whether:

- surgical treatment is effective in reducing symptoms and signs and in increasing nerve function;
- conservative treatment is effective in reducing symptoms and signs and in increasing nerve function;
- it is possible to identify the best treatment on the basis of clinical, neurophysiological, or nerve imaging assessment.

### Search methods

On 31 May 2016 we searched the Cochrane Neuromuscular Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, AMED, CINAHL Plus, and LILACS. We also searched PEDro (14 October 2016), and the papers cited in relevant reviews. On 4 July 2016 we searched trials registries for ongoing or unpublished trials.

### Selection criteria

The review included only randomised controlled clinical trials (RCTs) or quasi-RCTs evaluating people with clinical symptoms suggesting the presence of UNE. We included trials evaluating all forms of surgical and conservative treatments. We considered studies regarding therapy of UNE with or without neurophysiological evidence of entrapment.

### Data collection and analysis

Two review authors independently reviewed titles and abstracts of references retrieved from the searches and selected all potentially relevant studies. The review authors independently extracted data from included trials and assessed trial quality. We contacted trial investigators for any missing information.

## Main results

We identified nine RCTs (587 participants) for inclusion in the review, of which three studies were found at this update. The sequence generation was inadequate in one study and not described in three studies. We performed two meta-analyses to evaluate the clinical (3 trials, 261 participants) and neurophysiological (2 trials, 101 participants) outcomes of simple decompression versus decompression with submuscular or subcutaneous transposition; four trials in total examined this comparison.

We found no difference between simple decompression and transposition of the ulnar nerve for both clinical improvement (risk ratio (RR) 0.93, 95% confidence interval (CI) 0.80 to 1.08; moderate-quality evidence) and neurophysiological improvement (mean difference (in m/s) 1.47, 95% CI -0.94 to 3.87). The number of participants to clinically improve was 91 out of 131 in the simple decompression group and 97 out of 130 in the transposition group. Transposition showed a higher number of wound infections (RR 0.32, 95% CI 0.12 to 0.85; moderate-quality evidence).

In one trial (47 participants), the authors compared medial epicondylectomy with anterior transposition and found no difference in clinical and neurophysiological outcomes.

In one trial (48 participants), the investigators compared subcutaneous transposition with submuscular transposition and found no difference in clinical outcomes.

In one trial (54 participants for 56 nerves treated), the authors found no difference between endoscopic and open decompression in improving clinical function.

One trial (51 participants) assessed conservative treatment in clinically mild or moderate UNE. Based on low-quality evidence, the trial authors found that information on avoiding prolonged movements or positions was effective in improving subjective discomfort. Night splinting and nerve gliding exercises in addition to information provision did not result in further improvement.

One trial (55 participants) assessed the effectiveness of corticosteroid injection and found no difference versus placebo in improving symptoms at three months' follow-up.

## Authors' conclusions

We found only two studies of treatment of ulnar neuropathy using conservative treatment as the comparator. The available comparative treatment evidence is not sufficient to support a multiple treatment meta-analysis to identify the best treatment for idiopathic UNE on the basis of clinical, neurophysiological, and imaging characteristics. We do not know when to treat a person with this condition conservatively or surgically. Moderate-quality evidence indicates that simple decompression and decompression with transposition are equally effective in idiopathic UNE, including when the nerve impairment is severe. Decompression with transposition is associated with more deep and superficial wound infections than simple decompression, also based on moderate-quality evidence. People undergoing endoscopic surgery were more likely to have a haematoma. Evidence from one small RCT of conservative treatment showed that in mild cases, information on movements or positions to avoid may reduce subjective discomfort.

## PLAIN LANGUAGE SUMMARY

### Treatment for ulnar neuropathy at the elbow (UNE)

#### Review question

What are the effects of treatments for ulnar neuropathy at the elbow (UNE)?

#### Background

Ulnar neuropathy at the elbow is the second most common type of condition in which a nerve becomes trapped or compressed (the most common affects the wrist). The ulnar nerve travels down the side of the elbow. This nerve is important for movement and the sense of touch in the hand at the little finger side. Symptoms of UNE are tingling of the fourth and fifth finger at night, pain at the elbow, and a change in sense of touch if the elbow is bent for a long time. When UNE is severe, some hand muscles can become weak. Diagnosis is by the symptoms and signs of the condition, as well as neurophysiological tests. Treatment of UNE can be surgical or nonsurgical (e.g. splints, physical therapy, and rehabilitation). The best way to treat UNE remains unclear.

#### Study characteristics

We found two randomised controlled trials (RCTs) of nonsurgical treatment. One RCT compared three groups of people with mild or moderate UNE (51 people in total). All three groups received written instructions to avoid movements or positions that provoked symptoms. The second group had the same information with elbow splints at night for three months. The third group had the same information with nerve gliding exercises. The other nonsurgical study (55 people) compared a corticosteroid injection with a sham injection.

Seven RCTs compared different surgical methods:

- simple decompression or transposition of the nerve (submuscular or subcutaneous transposition) (4 trials, 327 participants);
- medial epicondylectomy or anterior transposition (1 trial, 47 participants);
- anterior subcutaneous transposition or anterior submuscular transposition (1 trial, 48 participants);
- keyhole or open surgery (1 trial, 54 participants with 56 trapped nerves).

### **Key results and quality of the evidence**

Written information alone was as effective in improving work activities and reducing pain at night as when people also used splints or did exercises.

Researchers found no evidence that corticosteroid injection was effective in improving symptoms of UNE.

We were able to combine results from three trials comparing two surgical techniques: simple decompression and transposition of the ulnar nerve (subcutaneous or submuscular). We found no important difference in symptom scores between the techniques at 6 to 12 months. Decompression with transposition may result in more deep and superficial wound infections. Trialists found no clinical differences between surgical techniques in the other surgical trials. People undergoing endoscopic surgery were more likely to have a haematoma (an abnormal collection of blood) after surgery.

Evidence was insufficient for us to choose the best treatment for UNE. However, we did find that in mild cases, information on movements and positions to avoid may reduce discomfort. Moreover, the combined results from three surgical trials provided moderate-quality evidence that simple decompression surgery and decompression with transposition may be equally effective, but that decompression with transposition may result in more deep and superficial wound infections.

The evidence is up to date to 31 May 2016.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Simple decompression versus transposition for ulnar neuropathy at the elbow						
<b>Patient or population:</b> people with ulnar neuropathy at the elbow <b>Settings:</b> surgery department <b>Intervention:</b> simple decompression <b>Comparison:</b> transposition						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Transposition	Simple decompression				
Proportion of participants with clinical improvement in function compared to baseline Follow-up: 6 to 12 months	746 per 1000 <sup>1</sup>	694 per 1000 (597 to 806)	RR 0.93 (0.8 to 1.08)	261 (3 studies)	⊕⊕⊕○ moderate <sup>2</sup>	
Subgroup: proportion of participants with clinical improvement in function compared to baseline - simple decompression versus subcutaneous transposition Follow-up: 12 months	730 per 1000 <sup>1</sup>	672 per 1000 (540 to 832)	RR 0.92 (0.74 to 1.14)	147 (1 study)	⊕⊕⊕○ moderate <sup>3</sup>	
Subgroup: proportion of participants with clinical improvement in function compared to baseline - simple	768 per 1000 <sup>1</sup>	730 per 1000 (591 to 899)	RR 0.95 (0.77 to 1.17)	114 (2 studies)	⊕⊕⊕○ moderate <sup>4</sup>	

decompression versus submuscular transposition Follow-up: 6 months					
Adverse events: proportion of participants with deep/superficial wound infections Follow-up: 6 to 12 months	115 per 1000 <sup>1</sup>	37 per 1000 (14 to 98)	RR 0.32 (0.12 to 0.85)	261 (3 studies)	⊕⊕⊕○ moderate <sup>2</sup>

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; RR: risk ratio

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup>The assumed risk was considered as the median of the risks in the control groups across studies. We did not consider the mean, since the number of studies was low, and the median is the best measure of central tendency in this case.

<sup>2</sup>Evidence downgraded once for study design (risk of bias). In one study, the method for sequence generation was not adequate and allocation concealment method was unclear. In two studies, allocation concealment method was unclear. In one study, the examiner was not blinded, and in another it was unclear if the examiner was blinded.

<sup>3</sup>Evidence downgraded once for study design. In the study contributing data for this outcome, the examiner was not blinded and allocation concealment method was unclear.

<sup>4</sup>Evidence downgraded once for study design. In one study, the method for sequence generation was not adequate and allocation concealment method was unclear, and in the other, the allocation concealment method was unclear. In one study, it was unclear if the examiner was blinded.

## BACKGROUND

### Description of the condition

Ulnar neuropathy at the elbow (UNE) is the second most common entrapment neuropathy after carpal tunnel syndrome. Its mean annual crude incidence is 24.7 cases per 100,000 person-years (Mondelli 2005). One of the sites of entrapment is the cubital tunnel. The tunnel is defined by Osbourne's ligament, the medial collateral ligament of the elbow, the elbow joint capsule, and the olecranon (Palmer 2010). The clinical picture is typically characterised by paraesthesias involving the fourth and fifth finger, pain at the elbow, sensory symptoms with prolonged flexion of the elbow, and in severe cases motor deficit of the ulnar innervated hand muscles (Dellon 1989). Diagnosis is based on signs, symptoms, and electrodiagnostic studies (Robertson 2005). Imaging, particularly ultrasound, in Beekman 2004, and magnetic resonance imaging (MRI), in Bordalo 2004, is gaining more attention as a sensitive diagnostic tool. Provocative clinical tests are not reliable or useful in the diagnosis of UNE (Beekman 2009). Electrodiagnostic examination is necessary to confirm the diagnosis, quantify the severity, and identify the exact site of ulnar nerve compression (AAEM 1999; Padua 2001).

### Description of the intervention

Treatment of UNE may be conservative (splint device, physical therapy, rehabilitation) or surgical (Bartels 2005a; Bartels 2005b; Biggs 2006). The goal of conservative treatment is to eliminate or reduce the frequency of external compression on the nerve (Dellon 1993; Robertson 2005). Regarding surgical therapy, many procedures are employed for the treatment of cubital tunnel syndrome, including simple decompression, anterior transposition (subcutaneous, submuscular, and intramuscular), and medial epicondylectomy (Eaton 1980; Kleinman 1989; Kuschner 1996; Tsai 1999; Robertson 2005).

### Why it is important to do this review

The basis for choosing a surgical technique must relate to the pathophysiology of the compression of the ulnar nerve at the elbow, an understanding of the aetiology of the ulnar nerve compression in a particular case, and the potential drawbacks of the various operative procedures. Despite the different options for treating UNE, optimal management remains controversial. This review was first published in 2010 and previously updated in 2012.

## OBJECTIVES

To determine the effectiveness and safety of conservative and surgical treatment in ulnar neuropathy at the elbow (UNE). We intended to test whether:

1. surgical treatment is effective in reducing symptoms and signs and in increasing nerve function;
2. conservative treatment is effective in reducing symptoms and signs and in increasing nerve function;
3. it is possible to identify the best treatment on the basis of clinical, neurophysiological, or nerve imaging assessment.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled clinical trials (RCTs) using truly random or quasi-random allocation of treatment. We would consider prospective, consecutive series of more than 10 participants where outcomes were collected by an observer other than the operating surgeon in the Discussion. We did not consider single-case reports.

#### Types of participants

People with clinical symptoms suggesting the presence of UNE with or without neurophysiological evidence of entrapment.

#### Types of interventions

All forms of surgical and conservative treatments.

#### Types of outcome measures

##### Primary outcomes

We defined the primary outcome measure as clinically relevant improvement in function compared to baseline. We assessed function with whatever scale was used by the trial authors, with a preference for validated scales such as the Disability of the Arm, Shoulder and Hand questionnaire, in Hudak 1996, or the UNE questionnaire (Mondelli 2006). When self administered scales were used, we would have evaluated if statistically significant changes were reported regarding the main scores in the questionnaires. We dichotomised the primary outcome measure into improvement or no improvement, regardless of the differences between the tools used. If a study evaluated more than one functional outcome measure, a better score on at least one of the functional outcome measures was enough to be considered as an improvement.



## Secondary outcomes

1. Change in neurological impairment measured by:
  - i) the strength of ulnar nerve innervated muscles with the Medical Research Council (MRC) sum score (BMRC 1976);
  - ii) the presence and extent of sensory deficit measured with whatever instrument was used by the authors, but with a preference for cotton wool or Semmes-Weinstein filaments (Bell-Krotoski 1987).
2. Change from baseline of the motor nerve conduction velocity across the elbow.
3. Change from baseline in the nerve diameter at the elbow, evaluated by ultrasound or MRI.
4. Change in quality of life.
5. Adverse events.

We evaluated primary and secondary outcomes at a short follow-up (one to six months) and at a long follow-up (between six months and two years).

## Search methods for identification of studies

### Electronic searches

On 31 May 2016, we searched the Cochrane Neuromuscular Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL) (in the Cochrane Register of Studies Online (CRSO)), MEDLINE (January 1966 to May 2016), Embase (January 1980 to May 2016), AMED (Allied and Complementary Medicine) (January 1985 to May 2016), CINAHL (Cumulative Index to Nursing and Allied Health Literature) Plus (January 1937 to May 2016), and LILACS (Latin American and Caribbean Health Science Information database) (January 1982 to May 2016). On 14 October 2016, we searched PEDro (Physiotherapy Evidence Database) (January 1980 to October 2016). We applied no limitations as to language.

The detailed search strategies are in the appendices: Cochrane Neuromuscular Specialised Register (Appendix 1), CENTRAL (Appendix 2), MEDLINE (Appendix 3), Embase (Appendix 4), AMED (Appendix 5), LILACS (Appendix 6), CINAHL Plus (Appendix 7), PEDro (Appendix 8), ClinicalTrials.gov (Appendix 9), and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (Appendix 10).

### Searching other resources

We searched the references of relevant trials identified by the search strategy and in June 2015 contacted authors of identified papers to determine whether other published or unpublished trials were available.

We also searched the following trials registers.

- ClinicalTrials.gov ([clinicaltrials.gov](http://clinicaltrials.gov)) (4 July 2016)
- WHO ICTRP ([who.int/ictpr/en/](http://who.int/ictpr/en/)) (4 July 2016)

## Data collection and analysis

### Selection of studies

Two review authors independently reviewed titles and abstracts of the references retrieved from the searches and selected all potentially relevant studies. We compared the results of our literature search to the review articles found using the previously mentioned databases. Furthermore, when information from one paper was republished by the same author in a larger investigation, or written in English, we considered only the most recent article. We obtained copies of these articles, and the same review authors independently reviewed them against the inclusion criteria of the review. The review authors then independently extracted data from included trials and assessed risk of bias with a data extraction form specifically designed for this purpose.

### Data extraction and management

We extracted the following data.

### Study methods

- Design (e.g. randomised or quasi-randomised, cohort study, case-control study)
- Randomisation method (including list generation)
- Method of allocation concealment
- Blinding method
- Stratification factors

### Participants

- Inclusion and exclusion criteria
- Number (total, per group)
- Age distribution
- Associated morbidities
- Treatments
- Pre-treatment quality of life and functional status, as measured by validated scales

### Intervention and control

- Type of therapy
- Type of control
- Details of control treatment including duration of non-operative treatment
- Concomitant treatments

### Follow-up data

- Duration of follow-up
- Loss to follow-up

### Outcome data

- British Medical Research Council (BMRC) scale
- Presence of sensory deficits (evaluated with cotton wool or Semmes-Weinstein filaments)
- Self administered scales including questionnaires assessing regional function and symptoms (Disability of the Arm, Shoulder and Hand questionnaire; UNE questionnaire; visual analogue scale (VAS) (Sriwatanakul 1983), and quality of life measures (such as the 36-Item Short Form Health Survey (SF-36)) (Ware 1992)
- Neurophysiology
- Ultrasound
- MRI

We considered the BMRC scale, presence of sensory deficits, and a regional self administered questionnaire the main outcome measures.

### Analysis data

- Methods of analysis (intention-to-treat or per-protocol analysis)
- Comparability of groups at baseline (age, gender, clinical impairment, neurophysiological impairment, associated diseases)
- Statistical techniques

### Other data

- Date
- Location
- Conflicts of interest
- Funding
- Single or multicentre

The first review author entered data into the Cochrane statistical software Review Manager 5, and the second review author checked the data entry.

At this update the review included information on trial funding and conflicts of interest.

### Assessment of risk of bias in included studies

We evaluated the risk of bias in the trials by scoring the following items and reported our assessments in the 'Risk of bias' tables:

- sequence generation;
- allocation concealment;
- blinding of participants;
- blinding of outcome assessors;
- incomplete outcome data;
- selective outcome reporting;
- other risk of bias.

We assessed the included studies under each domain and judged the risk of bias as 'high', 'low', or 'unclear'. We used unclear when

the report included insufficient information to make a judgement or when the risk of bias was uncertain (Higgins 2011).

### Measures of treatment effect

We used risk ratio (RR) estimations with 95% confidence intervals (CI) for binary outcomes and mean difference (MD) estimations with 95% CI for continuous outcomes. All analyses included all participants in the treatment groups to which they were allocated. If we had collected data from case-control studies, we would have considered using odds ratios and 95% CI.

### Dealing with missing data

In the first instance, we contacted study authors to supply data missing from included studies. We assessed missing data and drop-outs or attrition for each included study, and assessed and discussed the extent to which the missing data could have altered the results or conclusions of the review. If less than 70% of participants allocated to treatments provided data at the end of the trial for a particular outcome, we would have discarded those data as we would have considered them to be too prone to bias.

### Assessment of heterogeneity

We assessed clinical heterogeneity by comparing the distribution of important participant factors between trials (age, gender, clinical impairment, neurophysiological impairment, and associated diseases) and trial factors (randomisation concealment, blinding of outcome assessment, losses to follow-up, treatment type, and co-interventions). We assessed statistical heterogeneity by examining the  $I^2$  statistic, a quantity which approximately describes the proportion of variation in point estimates that is due to heterogeneity rather than sampling error. In addition, we planned to employ a  $\chi^2$  test to determine the strength of the evidence that heterogeneity was genuine.

### Assessment of reporting biases

In order to detect potential publication bias, we would plot RRs and 95% CIs against standard errors in each study (funnel plots). Asymmetry in such plots could be due to publication bias, but could also be due to a relationship between trial size and effect size. In the event of finding a relationship, we planned to examine the clinical diversity of the studies (Egger 1997).

### Data synthesis

Where the interventions were the same, or similar enough, we carried out a meta-analysis (DerSimonian 1986). We undertook statistical analysis using Review Manager 5 (RevMan 2014). We planned to synthesise results in a meta-analysis.

### 'Summary of findings' table

We included a 'Summary of findings' table for comparisons for which information from more than one study was available and assessed the quality of the body of evidence using the GRADE approach for the following outcomes:

- proportion of participants with clinically relevant improvement in function compared to baseline at 6 to 12 months (showing subgroups);
- change in quality of life;
- adverse events.

We downgraded the quality of the evidence for each outcome using the five GRADE considerations: limitations in design or implementation of studies suggesting a high risk of bias; indirectness of evidence; unexplained heterogeneity; imprecision; and high probability of publication bias (Schünemann 2011). RCTs start with a high quality assessment, which may be downgraded to moderate, low, or very low if these considerations are present to a serious degree.

### Subgroup analysis and investigation of heterogeneity

If possible, we would have conducted subgroup analysis for the following groups.

1. Two age groups: ( $\leq 45$  years old,  $> 45$  years old).
2. Two groups with different electrophysiological abnormalities, namely:
  - i) participants with pathological motor conduction velocity across the elbow and no other neurophysiological abnormality;
  - ii) participants with concomitant pathological motor conduction velocity across the elbow and one of the following criteria:
    - a) denervation signs in the ulnar innervated muscle of the hand; or
    - b) reduction of amplitude of sensory response in the fifth digit-wrist segment.

### Sensitivity analysis

If possible, we would have conducted sensitivity analyses to assess the impact of study quality. This would have included separate analyses of RCTs and quasi-RCTs.

### Adverse events

Since randomised studies rarely deal with adverse events adequately because the numbers are small and follow-up too short, we discussed adverse events (infections, worsening of symptoms) taking into account the non-randomised literature.

### Cost-benefit analyses

We considered cost-effectiveness of interventions in the [Discussion](#), where relevant data were available.

## RESULTS

### Description of studies

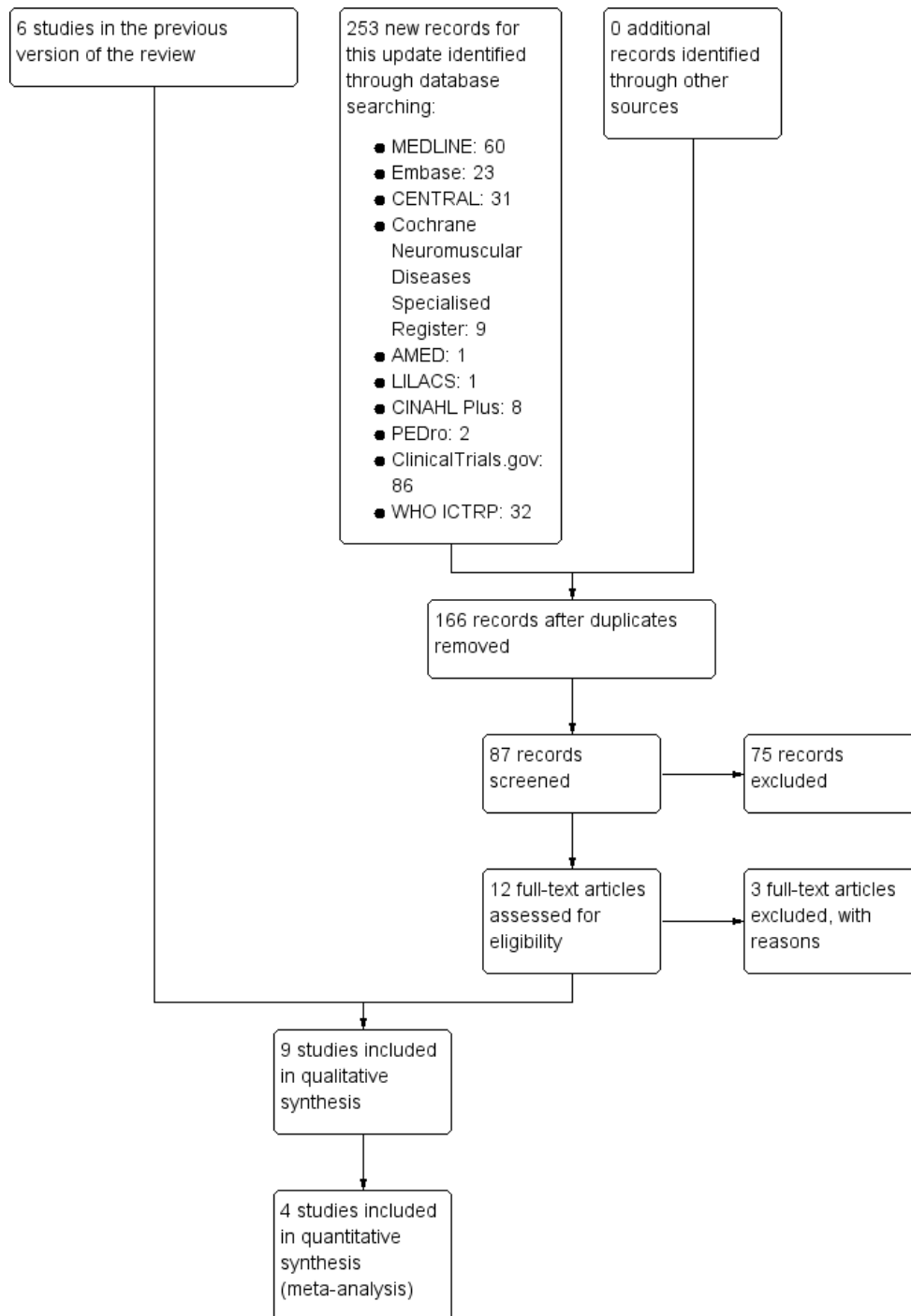
#### Results of the search

The previous version of this review included six studies. In 2016 we identified 253 new papers from database searches as potentially relevant and after we reviewed these, a total of nine RCTs (587 participants) met the inclusion criteria for the review. The following list reports the number of papers identified in each database by the new current strategies and the number newly identified at this update.

- MEDLINE: 264 (60 new papers)
- Embase: 137 (23 new papers)
- CENTRAL: 78 (31 new papers)
- Cochrane Neuromuscular Specialised Register: 31 (9 new papers)
- AMED: 15 (1 new paper)
- LILACS: 3 (1 new paper)
- CINAHL Plus: 74 (8 new papers)
- PEDro: 5 (2 new papers)
- ClinicalTrials.gov: 86
- WHO ICTRP: 32

[Figure 1](#) illustrates the study selection process.

**Figure 1. A flow diagram illustrating the study selection process.**



## Included studies

See [Characteristics of included studies](#).

To evaluate the clinical outcome we included three studies in the meta-analysis: [Bartels 2005](#) (152 participants; 5 lost to follow-up), [Gervasio 2005](#) (70 participants), and [Biggs 2006](#) (44 participants). The three studies compared simple decompression with transposition of the ulnar nerve. In two studies the latter was a sub-muscular transposition ([Gervasio 2005](#); [Biggs 2006](#)), and in one study, it was anterior subcutaneous transposition ([Bartels 2005](#)). A total of 131 participants were treated by simple decompression, and a total of 130 participants were treated by transposition of the nerve (submuscular or subcutaneous). In all three studies the participants had clinical and electrophysiological evidence of ulnar nerve impairment.

We performed two different evaluations to assess the effectiveness of surgery. In the first, we compared simple decompression with subcutaneous transposition ([Bartels 2005](#)), and in the second analysis, we compared simple decompression with submuscular transposition ([Gervasio 2005](#); [Biggs 2006](#)).

[Bartels 2005](#) and [Biggs 2006](#) used clinical scores to assess changes after surgical treatment. [Gervasio 2005](#) used a clinical score and a neurophysiological evaluation. The clinical outcome measures in the three studies varied. [Bartels 2005](#) used a clinical scale that included a combination of historical and physical findings (evaluation of sensation and muscular strength); [Biggs 2006](#) used the McGowan score and Louisiana State University Medical Center (LSUMC) score, both of which graded the sensory and muscular deficits; and [Gervasio 2005](#) evaluated the clinical picture preoperatively by Dellon's classification and postoperatively by the Bishop score. Dellon's staging system includes the assessment of sensory and motor function and the response to provocative tests. The Bishop score assesses objective and subjective parameters: grip strength, sensory measurement of static two-point discrimination, severity of residual symptoms, subjective improvement compared with the preoperative period, and preoperative and postoperative work status.

[Bartels 2005](#) performed a clinical follow-up at one year after surgery; [Biggs 2006](#) at six weeks and six months after surgery; and [Gervasio 2005](#) at six months after surgery (clinical and neurophysiological assessment). At the six-month follow-up, [Gervasio 2005](#) performed a neurophysiological assessment in all the participants in both groups. These investigators also performed a second clinical follow-up (the mean duration of the second follow-up was 47 months for the simple decompression group and 46.9 months for the anterior submuscular transposition group).

We also performed a meta-analysis of neurophysiological outcome, including two papers ([Gervasio 2005](#); [Nabhan 2005](#)).

[Nabhan 2005](#) (66 participants) compared two surgical procedures:

subcutaneous anterior transposition and decompression without transposition. Thirty-two participants underwent simple nerve decompression, and 34 had subcutaneous transposition. All participants had clinical and electrophysiological evidence of ulnar neuropathy. The main outcome measure was motor conduction velocity across the elbow, although the trialists also assessed muscular strength of ulnar innervated muscles pre- and postoperatively. All the participants in both groups underwent neurophysiological assessment. The investigators performed follow-up examinations at three months and nine months after surgery.

We included five other studies in the review but not in the meta-analyses ([Geutjens 1996](#); [Svernlöv 2009](#); [Zarezadeh 2012](#); [Schmidt 2014](#); [van Veen 2015](#)).

[Geutjens 1996](#) (47 participants) compared medial epicondylectomy with anterior transposition in people with clinical and electrophysiological evidence of ulnar neuropathy. The authors measured the clinical outcome by:

1. the MRC scale;
2. evaluation of sensation by light touch and static two-point discrimination; and
3. assessment of pain in the hand by a non-validated five-item scale.

The neurophysiological outcome was measured by ulnar motor nerve conduction velocity in all the participants in both groups. All the evaluations were performed before treatment and at 12 months. Participant satisfaction was assessed by a non-validated tool.

[Svernlöv 2009](#) (51 participants) compared three groups treated conservatively with:

1. night splinting for three months and "written information of the anatomy of the ulnar nerve, an explanation of the probable pathomechanics and the regimen regarding the avoidance of movements and positions provoking the symptoms";
2. nerve gliding exercises and the same written information;
3. written information only.

All the participants had clinically mild or moderate UNE, classified with the Dellon's staging system. All participants underwent electrophysiological assessment preoperatively, but only 12 participants had abnormal findings. The clinical outcome measures were: (1) evaluation of fifth-digit and grip strength, measured by two different dynamometers; and (2) the VAS. Electrophysiological outcomes were ulnar motor and sensory nerve conduction studies and electromyography. Participants assessed their symptoms according to the Canadian Occupational Performance Measure (COPM). The COPM is a 10-point scale that measures the person's own opinion of his or her ability to perform occupational activities and satisfaction with performance. The investigators evaluated the participants in the three groups before the treatment and at six months.

Zarezaadeh 2012 (48 participants) compared anterior subcutaneous transposition with anterior submuscular transposition in participants with clinical and electrophysiological evidence of ulnar neuropathy. The authors measured the clinical outcome by:

1. MRC scale;
2. subjective evaluation of muscle atrophy;
3. Yale Sensory Scale; and
4. VAS.

The authors measured the neurophysiological outcome by ulnar motor nerve conduction velocity in all participants but did not report the findings. All the evaluations were performed before treatment and at 12 months. The clinical outcome was assessed by a total score based on the results of the four outcome measures; however, no information was provided on the score generation process.

Schmidt 2014 (54 participants with 56 ulnar entrapments) compared endoscopic surgery with open decompression in people with clinical, neurophysiological, and ultrasonographic findings of ulnar neuropathy. The clinical outcome was measured by a modified Bishop scale, and the neurophysiological outcome by ulnar motor nerve conduction velocity. The trialists performed clinical and neurophysiological evaluations before surgery, during an early follow-up (a mean of 16 weeks), and a long-term follow-up (a mean of 16.8 months).

vanVeen 2015 (63 participants enrolled, 55 participants analysed) compared an ultrasound-guided injection of a 1 mL injection containing 40 mg methylprednisolone acetate and 10 mg lidocaine hydrochloride with a placebo injection. The trialists measured the clinical outcome by two subjective scales evaluating change in symptoms and severity of symptoms. Moreover, the trial authors evaluated the neurophysiological outcome by ulnar motor nerve conduction velocity and the ultrasonographic outcome by measur-

ing the ulnar nerve cross-section in a segment of 4 cm across the medial epicondyle.

## Excluded studies

See [Characteristics of excluded studies](#).

We excluded two studies from the review (Chen 2006; Zhong 2011). Chen 2006 compared two groups of participants. In the first group, participants “were immobilized with the plaster slab for an external fixation for 3 weeks” after operation; in the second group, they “began an immediate range of motion on the 2nd day after operation”. It seems that both groups were comprised of participants who underwent ulnar neurolysis or nerve anterior transposition. We excluded the study because the authors did not compare different therapeutic approaches, but rather two management approaches after surgery. From the translation it was difficult to evaluate the quality of the study. Zhong 2011 compared two groups of participants treated surgically. Participants in the first group were treated with subcutaneous transposition, and in the second group with submuscular transposition. The main outcome measures were the cross-sectional area (CSA) of the ulnar nerve at the elbow and neurophysiological parameters. The authors concluded that submuscular transposition produced greater improvement than subcutaneous transposition in severe cases. The preoperative values of CSA and of neurophysiological parameters were identical for the two compared groups in the report (even the same decimal values); since this is statistically improbable, we had serious concerns about the methodological quality of the work and therefore excluded it.

## Risk of bias in included studies

[Figure 2](#) summarises the risk of bias in the included RCTs.

**Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bartels 2005	+	?	?	-	+	?	-
Biggs 2006	+	?	?	?	+	+	-
Gervasio 2005	-	?	?	+	+	?	-
Geutjens 1996	?	+	?	+	+	+	-
Nabhan 2005	+	+	?	?	+	+	-
Schmidt 2014	?	?	+	+	+	+	+
Svernlöv 2009	?	+	-	+	+	+	?
vanVeen 2015	+	?	+	+	+	+	?
Zarezadeh 2012	+	?	?	?	+	-	-



## Allocation

Sequence generation was adequate in five studies (Bartels 2005; Nabhan 2005; Biggs 2006; Zarezaeh 2012; vanVeen 2015). Three studies did not clearly describe the method of sequence generation (Geutjens 1996; Svernløv 2009; Schmidt 2014). In one study the method of randomisation was inadequate (Gervasio 2005).

The allocation concealment method was described and adequate in three studies (Geutjens 1996; Nabhan 2005; Svernløv 2009). In six studies the method of allocation concealment was not described (Bartels 2005; Gervasio 2005; Biggs 2006; Zarezaeh 2012; Schmidt 2014; vanVeen 2015); we concluded that no allocation concealment procedure was used in these studies.

## Blinding

In six studies the authors did not describe if the participants were blinded (Geutjens 1996; Bartels 2005; Gervasio 2005; Nabhan 2005; Biggs 2006; Zarezaeh 2012); in two studies the participants were blinded (Schmidt 2014; vanVeen 2015); and in one study the participants were not blinded (Svernløv 2009).

In five studies the examiner was blinded (Geutjens 1996; Gervasio 2005; Svernløv 2009; Schmidt 2014; vanVeen 2015). In one study only a subgroup of 30 participants was evaluated by an independent examiner (Bartels 2005). In two studies the authors did not specify whether the examiner was blinded (Nabhan 2005; Biggs 2006). In one study the authors specified that the neurophysiological evaluation was blinded, but no information was reported about the assessment of clinical outcomes (Zarezaeh 2012).

## Incomplete outcome data

In three studies no participants were lost to follow-up (Gervasio 2005; Nabhan 2005; Zarezaeh 2012). In the remaining six studies a low number of participants were lost to follow-up: five participants (3.3%) in Bartels 2005, three (6.4%) in Biggs 2006, nine (4.7%) in Geutjens 1996, 13 (6.6%) in Svernløv 2009, three (5.5%) in Schmidt 2014, and five (5%) in vanVeen 2015. In the study evaluating conservative treatments (Svernløv 2009), six participants were dropouts because they underwent surgical decompression.

## Selective reporting

It was unclear whether two studies were free of selective outcome reporting (Bartels 2005; Gervasio 2005). In Bartels 2005, the methods listed two validated self report questionnaires (McGill Pain Questionnaire-Dutch language version (MPQ-DLV), SF-36), but provided no statistical information on the questionnaires in the results. The authors simply reported that the improvement

in the MPQ-DLV and SF-36 scores did not differ for participants treated with simple decompression or anterior subcutaneous transposition. In Gervasio 2005, trial authors performed the pre- and postoperative evaluations using two different staging systems: preoperatively the Dellon scale, and postoperatively the Bishop rating system. No information on the Dellon scale was available for the follow-up evaluation. In another study, the authors declared that all participants were neurophysiologically evaluated but reported no data (Zarezaeh 2012).

Six studies were free of selective outcome reporting (Geutjens 1996; Nabhan 2005; Biggs 2006; Svernløv 2009; Schmidt 2014; vanVeen 2015).

## Other potential sources of bias

In all nine trials the authors did not specify whether the study was designed to be a non-inferiority or a superiority trial (Geutjens 1996; Bartels 2005; Gervasio 2005; Nabhan 2005; Biggs 2006; Svernløv 2009; Zarezaeh 2012; Schmidt 2014; vanVeen 2015), and in eight trials the authors did not calculate sample size (Geutjens 1996; Bartels 2005; Gervasio 2005; Nabhan 2005; Biggs 2006; Svernløv 2009; Zarezaeh 2012; Schmidt 2014). In two studies, the clinical outcome measures used may have low sensitivity (Geutjens 1996; Nabhan 2005). One study only included people with severe neuropathy (Gervasio 2005).

Since none of the trials were at an overall high risk of bias, we did not conduct a sensitivity analysis.

## Effects of interventions

See: [Summary of findings for the main comparison](#) Simple decompression versus transposition for ulnar neuropathy at the elbow

### Surgery: simple decompression versus transposition

Bartels 2005, Biggs 2006, Gervasio 2005, and Nabhan 2005.

#### Primary outcome: proportion of participants with a clinically relevant improvement in function compared to baseline

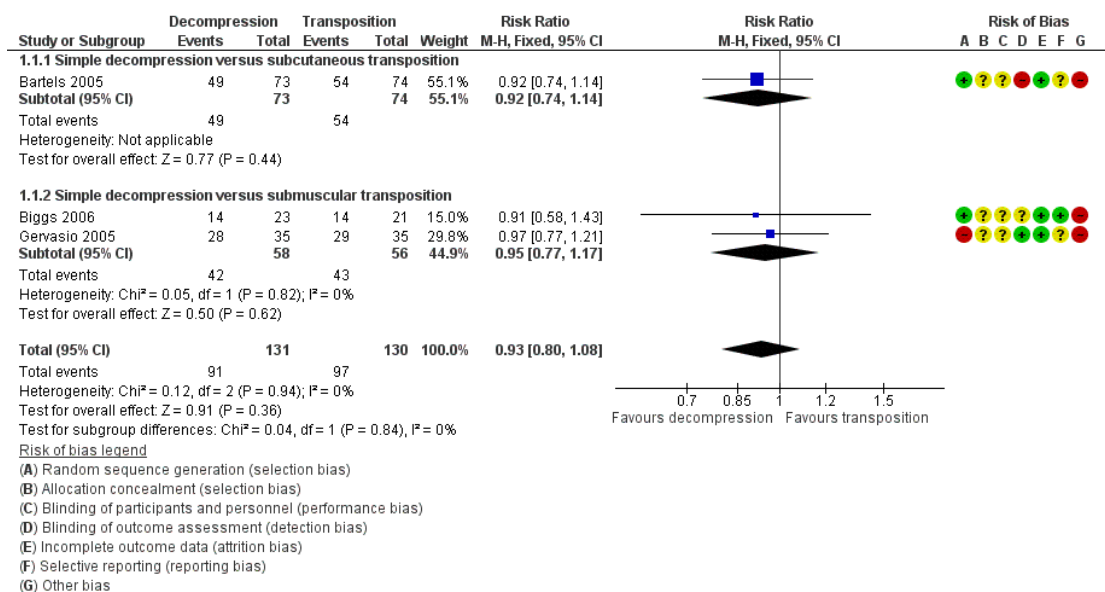
Reported in Bartels 2005, Biggs 2006, and Gervasio 2005. See [Summary of findings for the main comparison](#).

We found clinical improvement in 70% of participants treated with simple decompression and 75% of those treated with transposition in the period from 6 to 12 months after surgery. We found no significant difference in postoperative clinical improvement between simple decompression and transposition (subcutaneous or submuscular) of the ulnar nerve (RR 0.93, 95% CI 0.80 to 1.08; n = 261) (Analysis 1.1). Figure 3 shows the forest plot



for the studies in the meta-analysis. We observed no significant difference in clinical outcome between simple decompression and subcutaneous transposition (RR 0.92, 95% CI 0.74 to 1.14; n = 147) or between simple decompression and submuscular transposition (RR 0.95, 95% CI 0.77 to 1.17; n = 114) (Analysis 1.1; Figure 3).

**Figure 3. Forest plot of comparison: I Clinical and neurophysiological effect of simple decompression versus transposition, outcome: I.I Proportion of participants with clinical improvement in function compared to baseline.**



## Secondary outcomes

### Change in neurological impairment

Reported in Nabhan 2005.

Nabhan 2005 found a slight improvement in the mean value of the MRC sum scale (measuring specifically strength in ulnar intrinsic muscles) (BMRC 1976), and in the mean value of a non-validated sensory scale after simple decompression (pre-surgery MRC 4.0 ± 1.0, postsurgery MRC 4.5 ± 0.7) and after decompression with anterior subcutaneous transposition (pre-surgery MRC 3.8 ± 1.0, postsurgery MRC 4.3 ± 0.6). No difference was found between

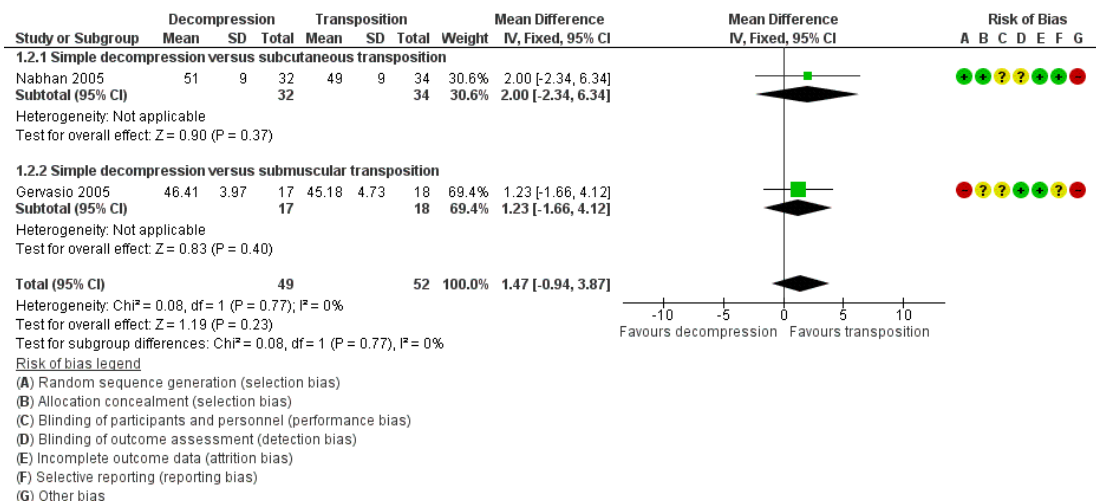
the two procedures.

### Change from baseline of the motor nerve conduction velocity across the elbow

Reported in Gervasio 2005 and Nabhan 2005.

We found a statistically significant improvement in motor nerve conduction velocity after simple decompression and after transposition at the six months' follow-up (Gervasio 2005; Nabhan 2005). We observed no difference in postoperative motor nerve conduction velocity (m/s) between the two procedures (MD 1.47, 95% CI -0.94 to 3.87; n = 101) (Analysis 1.2). Figure 4 shows the forest plot for this outcome.

**Figure 4. Forest plot of comparison: I Clinical and neurophysiological effect of simple decompression versus transposition, outcome: I.2 Postoperative motor nerve conduction velocity.**



For the [Gervasio 2005](#) study, we only included in the meta-analysis the participants who preoperatively had motor responses at the neurophysiological assessment (17 out of 35 participants in the simple decompression group and 18 out of 35 participants in the transposition group). The motor response, preoperatively absent in 18 participants in the simple decompression group, reappeared postoperatively in eight participants, while in the transposition group, it was absent in 17 participants and reappeared in six. Among the 30 participants with preoperative absence of sensory response in the simple decompression group, the sensory response reappeared in 16 participants. Among the 29 participants with absence of sensory response in the transposition group, the sensory response reappeared in 14 participants.

The available data did not allow a subgroup analysis between participants with pathological motor conduction velocity across the elbow only and participants who also had denervation signs or reduction of amplitude of sensory responses, or both, or between age groups.

#### **Change from baseline in the nerve diameter at the elbow evaluated by ultrasound or MRI**

No data were available on change from baseline in the ulnar nerve diameter at the elbow.

#### **Change in quality of life**

No data were available for the outcome change in quality of life.

#### **Adverse events**

Reported in [Bartels 2005](#), [Gervasio 2005](#), and [Biggs 2006](#).

Decompression with transposition was associated with a higher number of deep and superficial wound infections on meta-analysis of data from three trials (RR 0.32, 95% CI 0.12 to 0.85; n = 261; [Analysis 1.3](#)) (4 deep infections and 11 superficial infections in the transposition group, 0 deep infections and 5 superficial infections in the simple decompression group). Bartels and colleagues also found a higher scar area sensory loss in the transposition group (14 cases) than in the simple decompression group (2 cases). Other adverse events affected small numbers of participants.

#### **Surgery: medial epicondylectomy versus anterior transposition**

Studied in [Geutjens 1996](#).

#### **Primary outcome: proportion of participants with a clinically relevant improvement in function compared to baseline**

Clinical improvement in function was not evaluated.

#### **Secondary outcomes**

##### **Change in neurological impairment**

In [Geutjens 1996](#), the authors found no difference between medial epicondylectomy (n = 25) and anterior transposition (n = 22) in modifying muscular strength and sensory deficits after 12 months. After surgery, the number of participants with muscular deficits at the MRC grading was 13 in the medial epicondylectomy group

and 10 in the anterior transposition group ( $P = 0.119$ ). We were unable to report the grade 2 comparison as the data in the report were unclear. The mean ( $\pm$  standard deviation (SD)) two-point discrimination scores were  $6.8 \pm 2.8$  in the medial epicondylectomy group and  $9.2 \pm 3.3$  in the anterior transposition groups ( $P = 0.711$ ).

#### **Change from baseline of the motor nerve conduction velocity across the elbow**

Medial epicondylectomy and anterior transposition had similar efficacy on neurophysiological outcomes (postoperative motor nerve conduction velocity was  $32.6 \pm 7.55$  in the medial epicondylectomy group and  $34.0 \pm 8.01$  in the anterior transposition group,  $P = 0.772$ )

#### **Change from baseline in the nerve diameter at the elbow evaluated by ultrasound or MRI**

Not measured.

#### **Change in quality of life**

Not measured.

#### **Adverse events**

Postoperative pain in the hand occurred with anterior transposition. The mean (0-to-5 scale) pain score ( $\pm$  SD) after medial epicondylectomy ( $n = 25$ ) was  $0.0 (\pm 0)$  compared to  $0.45 \pm 0.86$  after anterior transposition ( $n = 22$ ) ( $P = 0.029$ ).

#### **Surgery: submuscular transposition versus anterior subcutaneous transposition**

Studied in [Zarezaheh 2012](#).

#### **Primary outcome: proportion of participants with a clinically relevant improvement in function compared to baseline**

Clinical improvement in function was not evaluated.

#### **Secondary outcomes**

##### **Change in neurological impairment**

In [Zarezaheh 2012](#), the authors found no difference between submuscular transposition ( $n = 24$ ) and anterior subcutaneous transposition ( $n = 24$ ) in improving sensory and strength deficits after 12 months. After surgery, in the submuscular group, 0% of

participants had absence of sensation, 50% had decreased or abnormal sensation, and 50% had normal sensation; in the subcutaneous group, 0% of participants had absence of sensation, 54.2% had decreased or abnormal sensation, and 45.8% had normal sensation ( $P = 1.0$ ). No participant in either group had severe strength deficits; 37.5% of participants in the submuscular group and 29.2% in the subcutaneous group had moderate deficits; and 62.5% in the submuscular group and 70.8% in the subcutaneous group had slight or no deficit. Submuscular transposition was associated with a greater pain reduction (after surgery, in the submuscular group, 0% of participants had severe pain, 12.5% had slight pain, and 87.5% had no pain; in the subcutaneous group, 0% of participants had severe pain, 66.7% had slight pain, and 33.3% had no pain;  $P = 0.0004$ ).

#### **Change from baseline of the motor nerve conduction velocity across the elbow**

The authors declare that neurophysiological studies were performed before and after treatment, but no data on the change from baseline of the motor conduction velocity across the elbow are available.

#### **Change from baseline in the nerve diameter at the elbow evaluated by ultrasound or MRI**

Not measured.

#### **Change in quality of life**

Not measured.

#### **Adverse events**

No adverse event was reported.

#### **Surgery: endoscopic versus open decompression**

Studied in [Schmidt 2014](#).

#### **Primary outcome: proportion of participants with a clinically relevant improvement in function compared to baseline**

The authors found no difference between the endoscopic group ( $n = 29$  nerves) and the open decompression group ( $n = 27$  nerves) in improving clinical function measured by Bishop score (early (mean 16 weeks) follow-up,  $P = 1.00$ ; long-term (mean 16.8 months) follow-up,  $P = 0.47$ ). In the endoscopic group at early follow-up, the clinical outcome, measured by the modified Bishop score, was poor in 2 arms, fair in 1, good in 11, and excellent in 15 arms. At long-term follow-up, the outcome was poor in 4 arms, fair in 1, good in 2, and excellent in 22 arms. In the open decompression group, at early follow-up the clinical outcome was poor in 3 arms,

fair in 1, good in 10, and excellent in 13 arms. At long-term follow-up, the outcome was poor in 5 arms, fair in 0, good in 3, and excellent in 19 arms.

## Secondary outcomes

### Change in neurological impairment

In [Schmidt 2014](#), the trial authors found no difference between the two procedures in improving pain at the sulcus or in the supplemented area of the nerve both in early follow-up ( $P = 0.84$ ) and late follow-up ( $P = 0.84$ ). In the endoscopic group, the post-operative value of numeric analogue scale (NAS) was 0.97 in the early follow-up and 0.64 in the long-term follow-up. In the open decompression group, the NAS score was 0.85 in the early follow-up and 0.79 in the long-term follow-up. Two-point discrimination was assessed, but no data comparing intervention groups were available.

### Change from baseline of the motor nerve conduction velocity across the elbow

At long-term follow-up, after a mean of 13.8 months, the authors found no difference between the procedures in improving electrophysiological findings (in the endoscopic group 21 cases out of 27 improved, and in the open group 22 out of 26 cases improved;  $P = 0.62$ ).

### Change from baseline in the nerve diameter at the elbow evaluated by ultrasound or MRI

Not measured.

### Change in quality of life

Not measured.

### Adverse events

A significantly higher rate of postoperative haematoma occurred in the endoscopic group (7/29 (24.14%) of arms in the endoscopic group and 1/27 (3.7%) of arms in the open group,  $P = 0.05$ ). No difference was found in the rate of disturbance of wound healing (3/29 (10.34%) of arms in the endoscopic group and 1/27 (3.7%) of arms in the open group,  $P = 0.61$ ).

### Conservative treatment: information provision versus information provision and nerve gliding exercises or versus information provision and night splinting

Assessed in one study ([Svernlöv 2009](#)).

### Primary outcome: proportion of participants with a clinically relevant improvement in function compared to baseline

In clinically mild or moderate UNE, night splinting plus information on the movements and positions provoking the symptoms ( $n = 26$ ), nerve gliding exercises plus information ( $n = 23$ ), and just information ( $n = 21$ ) determined an improvement of occupational activity at six-month follow-up ( $P = 0.0001$ ,  $P = 0.0003$ , and  $P = 0.039$ , respectively). Night splinting for three months and nerve gliding exercises did not provide further improvement in occupational activities and nocturnal pain at six months when compared with just information. Nerve gliding exercises and information alone improved satisfaction and diurnal pain ( $P = 0.0001$  for both treatments), while night splinting did not.

## Secondary outcomes

### Change in neurological impairment

Conservative treatments (night splinting plus information to avoid movements or positions provoking the symptoms, nerve gliding exercises plus information, and information alone) did not improve muscular strength ([Svernlöv 2009](#)).

### Change from baseline of the motor nerve conduction velocity across the elbow

Before treatment, 12 out of 51 participants had impaired nerve conduction velocity over the elbow segment. At six months' follow-up, 58% of these participants had normal conduction velocity.

### Change from baseline in the nerve diameter at the elbow evaluated by ultrasound or MRI

Not measured.

### Change in quality of life

Not measured.

### Adverse events

No adverse event was reported.

### Conservative treatment: corticosteroid injection versus placebo

Studied in [van Veen 2015](#).

### **Primary outcome: proportion of participants with a clinically relevant improvement in symptoms**

The authors found no difference between the corticosteroid group ( $n = 30$  participants) and the placebo group ( $n = 25$  participants) in improving symptoms at three months' follow-up ( $P = 0.871$ ). In the corticosteroid group, 9 out of 30 participants (30%) had a favourable outcome, and 21 participants (70%) had an unfavourable outcome. In the placebo group, 7 out of 25 participants (28%) had a favourable outcome, and 18 participants (72%) had an unfavourable outcome.

### **Secondary outcomes**

#### **Change in neurological impairment**

In [vanVeen 2015](#), at baseline and at follow-up the authors found no difference between the two groups regarding the severity of symptoms and the neurological examination findings. The authors reported data only at the baseline; no data are given at follow-up. At baseline in the corticosteroid group, 30 participants (100%) had sensory symptoms, and 5 participants (17%) had atrophy; the mean MRC score was 19.7 (range 18 to 20). In the placebo group, 25 participants (100%) had sensory symptoms and 5 participants (20%) had atrophy; the mean MRC score was 19.6 (range 15 to 20).

#### **Change from baseline of the motor nerve conduction velocity across the elbow**

The trial authors found no difference between the groups in improving electrophysiological findings at follow-up. The mean motor nerve conduction velocity across the elbow at follow-up was 48.3 m/s in the corticosteroid group ( $n = 26$ ) and 50.3 m/s in the placebo group ( $n = 23$ ) (these velocities were 45.1 m/s and 46.2 m/s at inclusion). The paper does not report SD, preventing calculation of a MD and 95% CI for the change.

#### **Change from baseline in the nerve diameter at the elbow evaluated by ultrasound or MRI**

The nerve cross-sectional area changed significantly ( $P = 0.043$ ) in the corticosteroid group ( $n = 26$ ), decreasing from 11.9 mm<sup>2</sup> to 10.9 mm<sup>2</sup>. In the placebo group ( $n = 23$ ), the cross-sectional area was unchanged (13.2 mm<sup>2</sup> at baseline and at follow-up). Without measures of variability, we were unable to calculate a MD and 95% CI.

#### **Change in quality of life**

Not measured.

### **Adverse events**

In the corticosteroid group, four participants experienced adverse events: one participant reported swelling at the injection site, one had pain at the injection site, one had a swollen hand, and one had depigmentation at the injection site. In the placebo group, one participant reported pain at the injection site.

## **DISCUSSION**

### **Summary of main results**

Participants who underwent surgical procedures in the included studies had, in the majority of cases, improved symptoms and nerve function, but there were no studies comparing surgical treatment to conservative management to support this in a controlled trial environment.

The available evidence suggests that simple decompression and decompression with transposition are equally effective in the treatment of the clinical and neurophysiological impairment of the ulnar nerve. Transposition is associated with a greater possibility of deep wound infections. In 2005, Bartels and colleagues performed a cost analysis in the Netherlands and found that the total median costs per patient were EUR 1124 for simple decompression and EUR 2730 for anterior subcutaneous transposition. This difference was mainly due to the costs related to sick leave, which was shorter for simple decompression ([Bartels 2005b](#)). In 2012, Song and colleagues performed a cost analysis and compared simple decompression, anterior subcutaneous transposition, anterior submuscular transposition, and medial epicondylectomy ([Song 2012](#)). They found that simple decompression yielded incremental cost-effectiveness ratios of less than USD 2027 per quality-adjusted life-year, and as a result was the most cost-effective treatment. Endoscopic and open decompression are equally effective in improving clinical function, but a significantly higher rate of postoperative haematoma occurred with the endoscopic approach. In clinically mild or moderate UNE, instructions to avoid movements or positions provoking the symptoms were sufficient to improve subjective discomfort, but the quality of the evidence was very poor (some bias, small numbers, electrophysiologically unconfirmed UNE in most cases, dropouts). Corticosteroid injection does not improve symptoms of UNE.

### **Overall completeness and applicability of evidence**

The available evidence is insufficient to identify the best treatment based on clinical, neurophysiological, and imaging characteristics. We did not think there was enough evidence to justify a multiple-treatment meta-analysis. Only two RCTs were available on the effectiveness of conservative treatments, and in one

of these studies only 24% of participants had neurophysiological evidence of UNE. No RCT compared a surgically treated UNE group and an untreated or conservatively treated group. Currently, the most common practice is to treat patients with mild symptoms and without muscular weakness conservatively, while surgery is reserved for cases that do not show benefit after conservative treatments or with severe neurological symptoms and signs (persistent paraesthesia, objective motor weakness, or muscular atrophy). Our meta-analysis suggests that simple decompression and decompression with transposition are equally effective in people with severe UNE, but simple decompression is associated with a lower rate of complications (wound infections and scar area sensory loss) than decompression with transposition. Not all studies measured adverse events.

No evidence was available on the effects of surgery on quality of life and imaging characteristics of the ulnar nerve at the elbow.

### Quality of the evidence

None of the studies identified and included in our meta-analysis was at an overall high risk of bias. All were small. All the studies were RCTs, which permitted evaluation of a group of participants with clinical and electrophysiological evidence of ulnar nerve impairment who were sufficiently representative of the UNE population. All degrees of severity of nerve impairment were considered, and the number of participants was high (261 participants for the clinical outcomes and 101 participants for the neurophysiological outcome). The follow-up rate was very high (only eight participants were lost to follow-up). The method used to generate the allocation sequence was adequate in three of the four RCTs included in the meta-analyses.

We observed no significant heterogeneity among studies, which allowed good precision of the estimated intervention effect. Some methodological problems must be highlighted. The four most important methodological weaknesses were:

1. an unblinded observer in one study (in two studies it was unclear whether the examiner was blinded);
2. inadequate sequence generation and unclear allocation concealment method in one study;
3. unclear allocation concealment method in two studies; and
4. no clear definition of the hypothesis being tested in all the studies.

Moreover, in all seven trials the authors neither specified whether the study was designed to be a non-inferiority or a superiority trial, nor did they calculate sample size.

### Potential biases in the review process

We believe the present review has a low likelihood of language or location bias. Indeed, we searched in different databases without any language limitations. We obtained translations of articles

written in languages other than English. We cannot exclude publication bias due to a higher rate of publication among studies with statistically significant effects, or time lag bias due to research findings published after our analysis of the literature.

### Agreements and disagreements with other studies or reviews

In a previous review on the surgical treatment of UNE (Zlowodzki 2007), the authors identified the same RCTs that we included in our meta-analysis up to that point. However, the authors used a different statistical approach. Zlowodzki and colleagues analysed the clinical scores as continuous variables and, because different scoring systems were used in each study, they applied a conversion of effect sizes (standardised mean difference). In accordance with our protocol, we dichotomised the primary outcome measure into improvement or no improvement, regardless of differences between the tools used. Despite the difference in statistical evaluation, Zlowodzki and colleagues concluded that simple decompression and decompression with transposition are equally effective. In their review, two different and not entirely comparable surgical techniques (submuscular and subcutaneous transposition) were considered together in the meta-analysis. We also performed a meta-analysis comparing submuscular transposition and simple decompression, and found no difference between the procedures. Macadam and colleagues used a similar approach in their review, but they also introduced non-randomised trials into the meta-analysis, with a higher likelihood of selection bias (Macadam 2008).

## AUTHORS' CONCLUSIONS

### Implications for practice

The available evidence is insufficient to identify the best treatment for idiopathic ulnar neuropathy at the elbow (UNE) on the basis of clinical, neurophysiological, and imaging characteristics. We do not know when to treat a person with UNE conservatively or surgically. However, the results of our meta-analysis provide moderate-quality evidence that simple decompression and decompression with transposition are equally effective in idiopathic UNE, including when the nerve impairment is severe, but decompression with transposition may result in more deep and superficial wound infections. In mild cases, evidence from one small randomised controlled trial (RCT) showed that providing information on movements or positions to avoid may reduce subjective discomfort.

### Implications for research

Future research in this area should include RCTs evaluating the

effectiveness of conservative treatments. These RCTs should use validated disease-specific clinical outcome measures, validated patient-oriented tools, neurophysiological measurements, and neuroimaging. Participants with homogeneous inclusion characteristics need to be included to adequately power the study.

An effort should be made to improve the methodology of RCTs examining surgical treatments. The most important aspects to include in future RCTs are:

1. the presence of a blinded examiner;
2. a clear description of the allocation concealment method;
3. validated disease-specific clinical outcome measures; and
4. a definition of the hypothesis the study is testing (is the study designed to be a non-inferiority or a superiority trial?).

Moreover, there is a need for a trial comparing conservative and surgical treatment.

## ACKNOWLEDGEMENTS

Ombretta Bugiani for her support in developing the literature research strategies (University of Siena).

Angela Meloni for her support in comparing the results of the different databases.

Michael Biggs and his coauthor for providing the raw data of their RCT.

This project was supported by the National Institute for Health Research (NIHR) via Cochrane Infrastructure funding to Cochrane Neuromuscular. The views and opinions expressed herein are those of the review authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service (NHS), or the Department of Health. Cochrane Neuromuscular is also supported by the MRC Centre for Neuromuscular Diseases.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Bartels 2005

Methods	RCT
Participants	152 people (age range 20 to 77 years; 94 male, 58 female) with signs and symptoms of idiopathic ulnar nerve entrapment, without benefit after conservative treatment and with electrophysiological evidence of the nerve impairment. Detailed description of exclusion criteria is available
Interventions	Simple decompression (75 participants), anterior subcutaneous transposition (77 participants)
Outcomes	Clinical outcome: <ol style="list-style-type: none"> <li>1. non-validated clinical scale including historical and clinical findings</li> <li>2. Dutch version of McGill Pain Questionnaire (MPQ-DLV)</li> <li>3. 36-Item Short Form Health Survey (SF-36)</li> </ol>
Conflicts of interest	No information provided.
Study funding	Supported by a grant from the National Health Insurance Board and the National Society of University Medical Centers
Notes	Operations performed between March 1999 and July 2002. Clinical follow-up at one year after surgery. Single-centre, the Netherlands

#### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation list
Allocation concealment (selection bias)	Unclear risk	No allocation concealment method is described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not specified.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Only a subgroup of 30 participants was evaluated by an independent examiner
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	Lost to follow-up: 2 participants in the simple decompression group (1 participant revoked informed consent, the other could not be traced), 3 participants in the anterior subcutaneous transposition group (1 was imprisoned, 2 could not be traced)

**Bartels 2005** (Continued)

Selective reporting (reporting bias)	Unclear risk	Quote: "The MPQ-DLV and SF-36 scores also improved with time. At any follow-up interval, there was no statistically significant difference in improvement between groups." Comment: No statistical information is available on the changes after surgery of the MPQ-DLV and SF-36 scores
Other bias	High risk	The sample size was not calculated. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial

**Biggs 2006**

Methods	RCT
Participants	44 people (age range 27 to 83 years; 33 male, 11 female) with signs and symptoms of idiopathic ulnar nerve entrapment, without benefit after conservative treatment and with electrophysiological evidence of the nerve impairment. Exclusion criteria included: <ol style="list-style-type: none"> <li>1. repeat surgery;</li> <li>2. prior fracture or dislocation at the elbow;</li> <li>3. tumours;</li> <li>4. subluxing ulnar nerve syndrome;</li> <li>5. unwillingness to participate in the study.</li> </ol>
Interventions	Simple decompression (23 participants), submuscular transposition (21 participants)
Outcomes	Clinical outcome: <ol style="list-style-type: none"> <li>1. 4-tiered McGowan grading system</li> <li>2. 6-tiered Louisiana State University Medical Center (LSUMC) grading system</li> </ol>
Conflicts of interest	No information provided.
Study funding	No information provided.
Notes	Operations were performed between August 1993 and June 1998 by a single surgeon in 2 hospitals in Australia. Follow-up at 6 weeks and 6 months after surgery

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Unclear risk	No allocation concealment method is described.
Blinding of participants and personnel (performance bias)	Unclear risk	Not specified.

**Biggs 2006** (Continued)

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not specified.
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	Quote: "Three patients were lost to follow-up"
Selective reporting (reporting bias)	Low risk	Results from all the outcome measures are reported.
Other bias	High risk	The sample size was not calculated. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial

**Gervasio 2005**

Methods	RCT
Participants	70 people (age range 32 to 75 years; 48 male, 22 female) with severe cubital tunnel syndrome, grade 3 according to Dellon's staging system. All the participants had electrophysiological evidence of ulnar impairment. Exclusion criteria: <ol style="list-style-type: none"> <li>1. cubitus valgus</li> <li>2. osseous canal deformity (previous traumatic events or severe osteophytosis of the elbow joint)</li> <li>3. luxation of the nerve</li> <li>4. dislocation of the medial portion of the triceps</li> <li>5. severe medical or anaesthesiological problems, or both</li> </ol>
Interventions	Simple decompression (35 participants), anterior submuscular transposition (35 participants)
Outcomes	Clinical outcome: Bishop rating system, which assesses subjective and objective parameters Electrophysiological outcome: <ol style="list-style-type: none"> <li>1. distal motor latency</li> <li>2. compound muscle action potential amplitude</li> <li>3. nerve conduction velocity</li> </ol>
Conflicts of interest	"The authors ... have no personal or institutional financial interest in drugs, materials, or devices described in this study."
Study funding	"The authors have received no financial support in conjunction with the compilation of this study"
Notes	Operations were performed between February 1998 and June 2003 at a single centre in Italy. There were 2 surgeons, each of whom performed the operation in 1 of the 2 groups. Follow-up at 6 months after surgery

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "The patients were randomised by use of their reservation numbers in the hospital"
Allocation concealment (selection bias)	Unclear risk	No allocation concealment method is described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not specified.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The postoperative outcome, both clinical and electroneuromyographic, was evaluated in all the patients by the same blinded evaluator"
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	No participant lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Pre- and postoperative evaluations were performed using 2 different staging systems: preoperatively the authors used the Del-lon scale, postoperatively they used the Bishop rating system
Other bias	High risk	The sample size was not calculated. Only people with severe disease were included in the study. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial

## Geutjens 1996

Methods	RCT
Participants	52 people (age range 36 to 85 years) with clinical and neurophysiological evidence of ulnar nerve impairment at the elbow. Exclusion criteria: <ol style="list-style-type: none"> <li>1. rheumatoid disease at the elbow</li> <li>2. valgus deformity, defined as a carrying angle of more than 5° greater than the opposite elbow</li> </ol>
Interventions	Medial epicondylectomy (25 cases), anterior transposition (22 cases)
Outcomes	Clinical outcomes: <ol style="list-style-type: none"> <li>1. MRC scale</li> <li>2. presence of paraesthesiae</li> <li>3. 2-point discrimination</li> </ol> Electrophysiological outcome (in all the participants in both groups): motor nerve conduction velocity Patient satisfaction assessed by a non-validated tool.

Conflicts of interest	Report states: “No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article”	
Study funding	No information provided.	
Notes	Operations performed between 1985 and 1992. Appears to be a single-centre study, UK. 2 surgeons both performed each procedure. Follow-up at 12 months after surgery	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation is not clearly described.
Allocation concealment (selection bias)	Low risk	The participants “were randomly allocated to one of the two operations by the use of sealed envelopes which were only opened in the operating theatre just before the procedure”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not specified.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “Neurological assessments were blinded as regards the operation and made without exposing the elbow”
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	Quote: “52 patients had operations for ulnar neuropathy and were entered into the study. Nine were lost to follow-up of whom two had died, records were untraceable in four, and three had moved away and could not be contacted”. 43 participants were evaluated at the follow-up, of whom 4 had bilateral operations
Selective reporting (reporting bias)	Low risk	Results from all the outcome measures are reported.
Other bias	High risk	The outcome measures used to evaluate clinical improvement in terms of sensation and motor strength may have a low sensitivity. The sample size was not calculated. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial

Methods	RCT
Participants	66 people (mean age 52 years, SD 12; 38 males, 28 females) with clinical and electrophysiological evidence of ulnar nerve neuropathy Exclusion criteria: previous traumas to the elbow causing deformity or distortion of the cubital tunnel, as well as recurrent cubital tunnel syndrome after previous surgery
Interventions	Simple decompression (32 participants), decompression and anterior subcutaneous transposition (34 participants)
Outcomes	Clinical outcomes: 1. Yale Sensory Scale 2. MRC scale 3. VAS Electrophysiological outcome: motor nerve conduction velocity
Conflicts of interest	No information provided.
Study funding	No information provided.
Notes	Operations performed between August 2001 and October 2003. Single centre in Germany. Follow-up examinations at 3 and 9 months after surgery. The sample size was not calculated. Only people with severe disease were included in the study. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was carried out by drawing cards in sealed envelopes"
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation was carried out by drawing cards in sealed envelopes"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not specified.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "All patients underwent nerve conduction velocity studies pre-operatively by two blinded neurophysiologists according to a standard protocol" Comment: It is not specified if the postoperative evaluation was performed by blinded examiners
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	No participant lost to follow-up.
Selective reporting (reporting bias)	Low risk	Results from all the outcome measures are reported.

**Nabhan 2005** (Continued)

Other bias	High risk	The outcome measures used to evaluate clinical improvement in terms of sensation and motor strength may have a low sensitivity. The sample size was not calculated. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial
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**Schmidt 2014**

Methods	RCT
Participants	54 people (mean age 49.3 years, range 20 to 74; 32 males, 22 females) with 56 clinical, electrophysiological, and ultrasonographic confirmed cases of ulnar nerve neuropathy Exclusion criteria: contraindications for general anaesthesia, post-traumatic cubital tunnel syndrome with bony deformity of the elbow, previous surgery of the affected ulnar nerve, severe nerve luxation Investigators appear to have randomised arms rather than participants
Interventions	Endoscopic decompression (29 arms), open decompression (27 arms)
Outcomes	Clinical outcomes: 1. modified Bishop scale 2. 2-point discrimination 3. numeric analogue scale (NAS) Electrophysiological outcome: motor nerve conduction velocity
Conflicts of interest	Report states: "The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article."
Study funding	No information provided.
Notes	Operations were performed between October 2008 and April 2011. Single centre in Germany. Early follow-up at mean of 16 weeks and long-term follow-up at mean of 16.8 months

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The randomization process was performed as a simple randomization without restrictions by drawing a trial envelope by the surgeon directly before each surgery started"
Allocation concealment (selection bias)	Unclear risk	Quote: "The randomization process was performed as a simple randomization without restrictions by drawing a trial envelope by the surgeon directly before each surgery started"



**Schmidt 2014** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded examiners performed the postoperative evaluation and statistical analysis
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	3 participants were free of symptoms at follow-up and declined further electrophysiological examination
Selective reporting (reporting bias)	Low risk	Results from all the outcome measures are reported.
Other bias	Low risk	The sample size was not calculated. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial It is unclear whether any adjustment was made for the 2 bilateral cases (3.7%), but unlikely to have an important effect

**Svernlöv 2009**

Methods	RCT
Participants	70 people (age range 17 to 72 years; 31 male, 39 female) with clinical mild or moderate ulnar neuropathy at the elbow classified with the Dellon's staging system. 12 participants only had abnormal findings at the electrophysiological evaluation. Exclusion criteria: "Patients with past or present symptoms of neck problems, clinical signs of another nerve problem, previous trauma or surgery to the same arm, arthritis or palpable swelling at the elbow or subluxations of the ulnar nerve"
Interventions	<ol style="list-style-type: none"> <li>1. night splinting for 3 months and "written information of the anatomy of the ulnar nerve, an explanation of the probable pathomechanics and the regimen regarding the avoidance of movements and positions provoking the symptoms" (21 participants)</li> <li>2. nerve gliding exercises and written information (15 participants)</li> <li>3. written information only (15 participants)</li> </ol>
Outcomes	<p>Clinical outcome:</p> <ol style="list-style-type: none"> <li>1. strength of the fifth digit and grip strength measured by 2 different dynamometers</li> <li>2. VAS</li> </ol> <p>Electrophysiological outcome (preoperatively performed in all participants, postoperatively in 45 participants): ulnar motor and sensory nerve conduction studies, electromyography</p> <p>Participants assessed their symptoms according to the Canadian Occupational Performance Measure (COPM)</p>
Conflicts of interest	No information provided.
Study funding	No information provided.

**Svernlöv 2009** (Continued)

Notes	Performed between March 1997 and December 2000. Follow-up at 6 months after surgery. 2 centres, Denmark and Sweden	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation is not clearly described.
Allocation concealment (selection bias)	Low risk	Quote: "patients were then randomised using sequentially numbered, sealed envelopes into three groups for different treatments"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Another, independent, occupational therapist at each centre evaluated the patients before and 6 months after starting the study"
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	Quote: "Thirteen patients ... in the primarily randomized patients completed the programme but were unavailable for the follow-up at 6 months. Six did not attend because of practical or personal reasons and seven had developed other symptoms (such as carpal tunnel syndrome, epicondylalgia, impingement syndrome or neck pain). Another six patients, two from each group, underwent surgical decompression because of persistent symptoms"
Selective reporting (reporting bias)	Low risk	Results from all the outcome measures are reported.
Other bias	Unclear risk	The sample size was not calculated. The authors do not specify if the study was designed to be a non-inferiority or a superiority trial. Only 24% of participants had neurophysiological evidence of UNE

**vanVeen 2015**

Methods	RCT
Participants	63 people were randomised, but 55 people were statistically analysed (in the intervention group mean age 56 years, range 29 to 91; in the placebo group mean age 53 years, range 24 to 76). All the participants had clinical and neurophysiological or ultrasonographic evidence of ulnar nerve neuropathy Exclusion criteria: recurrence of UNE, age < 18 years, oral prednisolone or anticoagulant drugs, known allergy to prednisolone, history of subluxation of the ulnar nerve at the

	elbow
Interventions	Ultrasound-guided injection of 1 mL containing 40 mg methylprednisolone acetate and 10 mg lidocaine hydrochloride (30 participants), or a placebo injection with 1 mL of sodium chloride 0.9% (25 participants)
Outcomes	<p>Clinical outcome:</p> <ol style="list-style-type: none"> <li>1. subjective change in symptoms measured by a not-validated scale</li> <li>2. subjective grading of symptoms severity measured by a not-validated scale</li> </ol> <p>Electrophysiological outcome (preoperatively performed in all participants, postoperatively in 48 participants): ulnar motor nerve conduction velocity</p> <p>Ultrasonographic outcome: cross-sectional area of ulnar nerve in a segment of 4 cm across the medial epicondyle</p>
Conflicts of interest	No information provided.
Study funding	No information provided.
Notes	Participants enrolled between September 2009 and April 2014 at the neurology outpatient clinic of the Medical Centre Haaglanden, Netherlands. Follow-up at 3 months after treatment

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed using a random number table.
Allocation concealment (selection bias)	Unclear risk	No allocation concealment method is described.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were blinded. "The physician who collected and entered the data was blinded". Treatment allocation was known during the analysis
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessment was performed by a blinded physician.
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	Among the 34 participants allocated to the corticosteroid group, 1 participant was not treated because of withdrawal of consent before injection. 3 participants were lost at follow-up and were not analysed for the primary outcome; a total of 7 participants did not undergo ultrasonography, and 7 did not undergo electrophysiological tests. Among the 29 participants allocated to the placebo group, 2 participants did not receive placebo, 1 participant with symptoms recovered before injection, and 1 participant had previously had surgery. 2 participants were lost at follow-up and not evaluated for the primary outcome; a total of

		4 participants did not undergo ultrasonography, and 5 did not undergo electrophysiological tests
Selective reporting (reporting bias)	Low risk	Results from all outcome measures are reported.
Other bias	Unclear risk	The authors do not specify if the study was designed to be a non-inferiority or a superiority trial

## Zarezadeh 2012

Methods	RCT
Participants	48 participants were enrolled in the study (age range 25 to 60 years; 27 male, 21 female) with clinical and neurophysiological evidence of ulnar nerve impairment at the elbow. The trial authors declare: "according to clinical and paraclinical tests, severe and moderate patients and mild group that did not respond to conservative treatment were operated"; however, they do not indicate how the severity was defined. Exclusion criteria included deformity or distortion of the cubital tunnel due to previous trauma to the elbow and recurrent cubital tunnel syndrome after previous surgery
Interventions	Anterior subcutaneous transposition (24 participants), anterior submuscular transposition (24 participants)
Outcomes	Clinical outcomes: 1. Yale Sensory Scale, 2. MRC Scale 3. VAS 4. subjective evaluation of muscle atrophy
Conflicts of interest	None declared.
Study funding	None
Notes	Operations performed between October 2008 and March 2009. Single centre, Iran. Electrophysiological evaluation was performed before and 12 months after surgery, but no data are available

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "based on a random table numbers, generated by the random allocation software, the principal investigator allocated patients into two groups"
Allocation concealment (selection bias)	Unclear risk	Quote: "based on a random table numbers, generated by the random allocation software, the principal investigator allocated patients into two groups"

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "To prevent bias, all patients underwent double-blind nerve conduction velocity studies, conducted by two neuro-physiologists according to a standard protocol, before and after surgery" Comment: Despite this quote, the authors do not unequivocally state that the participants were blinded to the treatment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "To prevent bias, all patients underwent double-blind nerve conduction velocity studies" Comment: It is not specified if the clinical outcomes were assessed by a blinded examiner
Incomplete outcome data (attrition bias) Clinical or neurophysiological outcome	Low risk	No participant was lost to follow-up.
Selective reporting (reporting bias)	High risk	No neurophysiological data are available.
Other bias	High risk	The sample size was not calculated. The trial authors do not specify if the study was designed to be a non-inferiority or a superiority trial

MRC: Medical Research Council  
 RCT: randomised controlled trial  
 SD: standard deviation  
 UNE: ulnar neuropathy at the elbow  
 VAS: visual analogue scale

### Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
<a href="#">Chen 2006</a>	The authors do not compare therapeutic approaches.
<a href="#">Zhong 2011</a>	The preoperative values of cross-sectional area and of neurophysiological parameters are identical for the 2 compared groups (even the same decimal values). Since this is statistically improbable, we have serious concerns about the methodological quality of the work

## DATA AND ANALYSES

### Comparison 1. Clinical and neurophysiological effect of simple decompression versus transposition

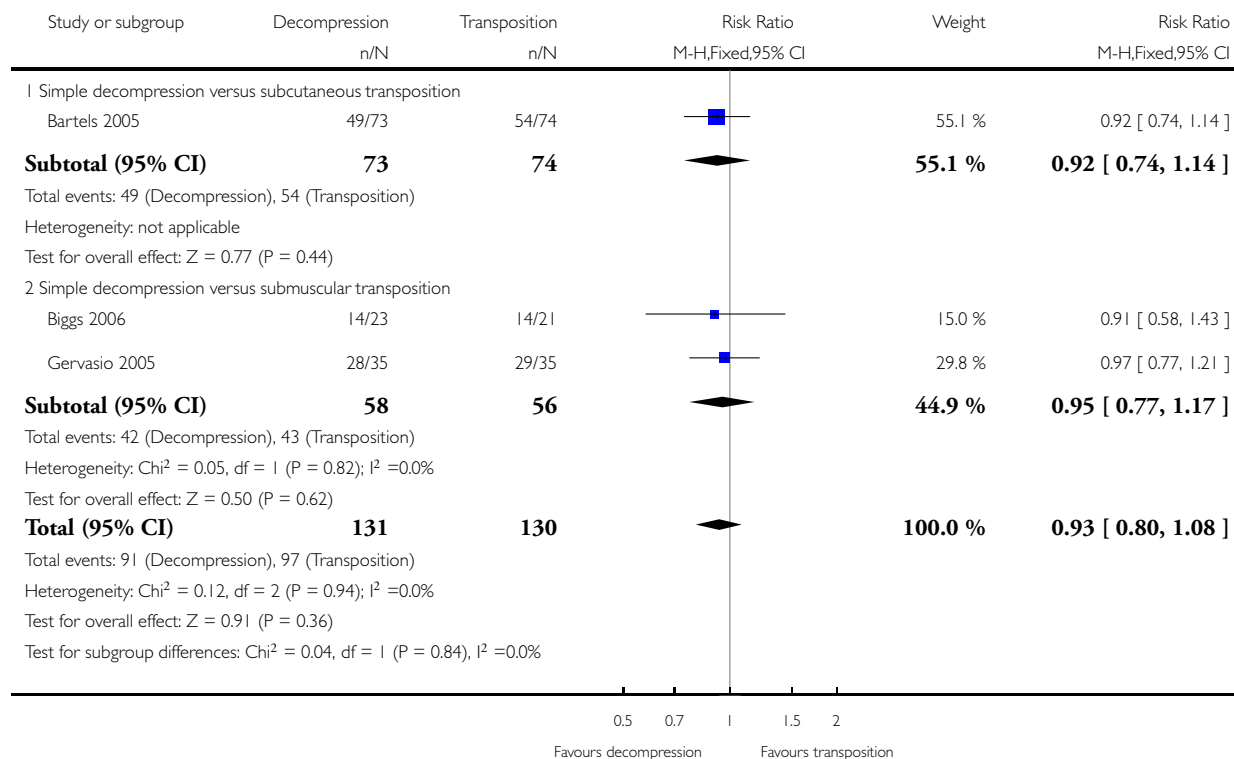
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion of participants with clinical improvement in function compared to baseline	3	261	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.80, 1.08]
1.1 Simple decompression versus subcutaneous transposition	1	147	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.74, 1.14]
1.2 Simple decompression versus submuscular transposition	2	114	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.77, 1.17]
2 Postoperative motor nerve conduction velocity	2	101	Mean Difference (IV, Fixed, 95% CI)	1.47 [-0.94, 3.87]
2.1 Simple decompression versus subcutaneous transposition	1	66	Mean Difference (IV, Fixed, 95% CI)	2.0 [-2.34, 6.34]
2.2 Simple decompression versus submuscular transposition	1	35	Mean Difference (IV, Fixed, 95% CI)	1.23 [-1.66, 4.12]
3 Proportion of participants with deep/superficial wound infections	3	261	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.12, 0.85]

**Analysis 1.1. Comparison 1 Clinical and neurophysiological effect of simple decompression versus transposition, Outcome 1 Proportion of participants with clinical improvement in function compared to baseline.**

Review: Treatment for ulnar neuropathy at the elbow

Comparison: 1 Clinical and neurophysiological effect of simple decompression versus transposition

Outcome: 1 Proportion of participants with clinical improvement in function compared to baseline

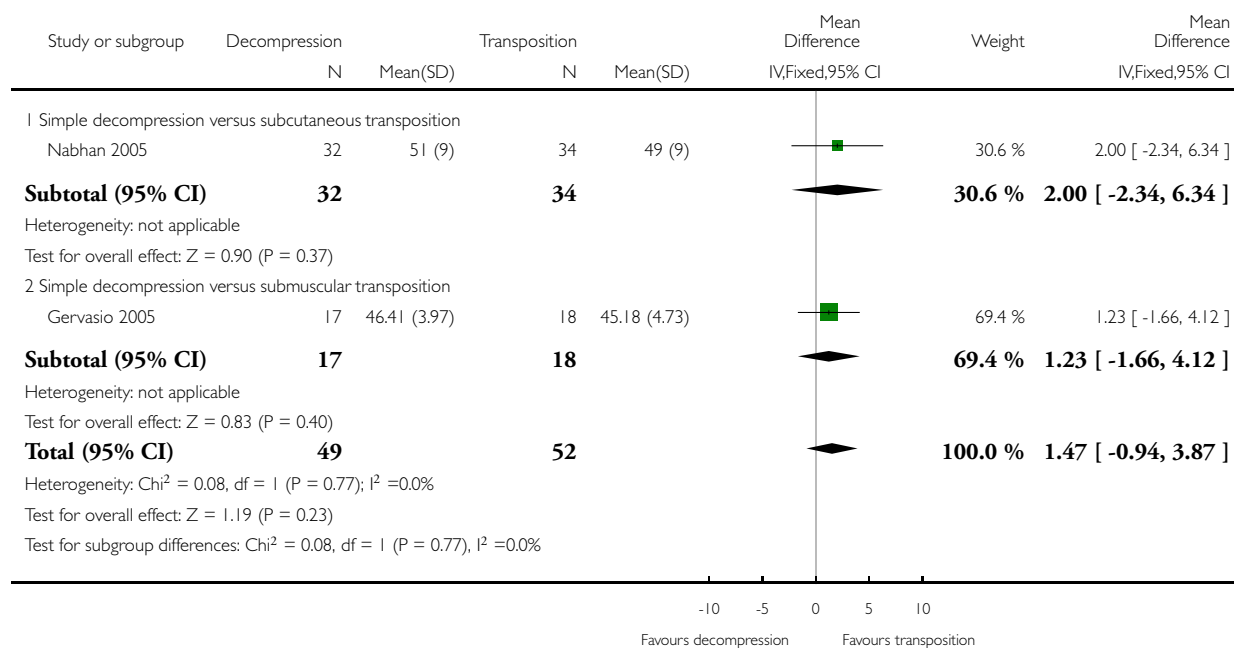


## Analysis 1.2. Comparison 1 Clinical and neurophysiological effect of simple decompression versus transposition, Outcome 2 Postoperative motor nerve conduction velocity.

Review: Treatment for ulnar neuropathy at the elbow

Comparison: 1 Clinical and neurophysiological effect of simple decompression versus transposition

Outcome: 2 Postoperative motor nerve conduction velocity



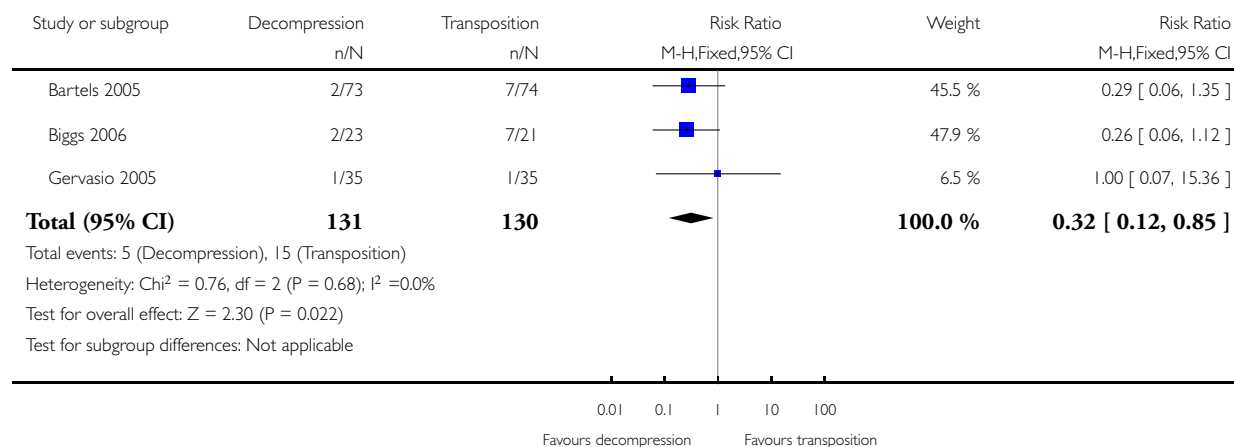


### Analysis 1.3. Comparison 1 Clinical and neurophysiological effect of simple decompression versus transposition, Outcome 3 Proportion of participants with deep/superficial wound infections.

Review: Treatment for ulnar neuropathy at the elbow

Comparison: 1 Clinical and neurophysiological effect of simple decompression versus transposition

Outcome: 3 Proportion of participants with deep/superficial wound infections



## APPENDICES

### Appendix 1. Cochrane Neuromuscular Specialised Register (CRS) search strategy

#1 MeSH DESCRIPTOR Ulnar Neuropathies Explode All [REFERENCE] [STANDARD]

#2 “ulnar neuropath\*” or “ulnar nerve” or “compression syndrome\*” [REFERENCE] [STANDARD]

#3 #1 or #2 [REFERENCE] [STANDARD]

#4 elbow [REFERENCE] [STANDARD]

#5 #3 and #4 [REFERENCE] [STANDARD]

#6 “cubital tunnel syndrome” [REFERENCE] [STANDARD]

#7 #5 or #6 [REFERENCE] [STANDARD]

#8 (#5 or #6) AND (INREGISTER) [REFERENCE] [STANDARD]

## Appendix 2. CENTRAL search strategy

#1 elbow  
#2 ulnar next neuropath\*  
#3 ulnar next nerve\*  
#4 nerve next compression  
#5 #2 or #3 or #4  
#6 #1 and #5  
#7 cubital next tunnel  
#8 #6 or #7

## Appendix 3. MEDLINE (OvidSP) search strategy

Ovid MEDLINE(R) 1946 to May Week 3 2016

Database: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

-----  
1 randomized controlled trial.pt. (417272)  
2 controlled clinical trial.pt. (90753)  
3 randomized.ab. (354957)  
4 placebo.ab. (172532)  
5 drug therapy.fs. (1860309)  
6 randomly.ab. (254384)  
7 trial.ab. (367092)  
8 groups.ab. (1586892)  
9 or/1-8 (3789565)  
10 exp animals/ not humans.sh. (4247320)  
11 9 not 10 (3266063)  
12 Ulnar Neuropathies/ or ulnar neuropath\$.tw. or Ulnar Nerve Compression Syndromes/ or Ulnar Nerve/ or ulnar nerve\$.tw. (9958)  
13 Elbow/ or elbow\$.tw. (27662)  
14 12 and 13 (2081)  
15 Cubital Tunnel Syndrome/ or (cubital tunnel adj5 syndrome\$.tw. (667)  
16 14 or 15 (2452)  
17 11 and 16 (265)  
18 remove duplicates from 17 (264)

## Appendix 4. Embase (OvidSP) search strategy

Database: Embase <1980 to 2016 Week 22>

Search Strategy:

-----  
1 crossover-procedure.sh. (47128)  
2 double-blind procedure.sh. (128476)  
3 single-blind procedure.sh. (22118)  
4 randomized controlled trial.sh. (401880)  
5 (random\$ or crossover\$ or cross over\$ or placebo\$ or (doubl\$ adj blind\$) or allocat\$).tw.ot. (1252828)  
6 trial.ti. (199320)  
7 or/1-6 (1402288)  
8 (animal/ or nonhuman/ or animal experiment/) and human/ (1483388)  
9 animal/ or nonanimal/ or animal experiment/ (3570735)

10 9 not 8 (2954815)  
 11 7 not 10 (1290837)  
 12 limit 11 to embase (1064995)  
 13 Cubital Tunnel Syndrome/ or (Cubital Tunnel adj5 Syndrome).tw. (2023)  
 14 ulnar neuropath\$.tw. or ulnar nerve/ or ulnar nerve.tw. or nerve compression/ (21186)  
 15 elbow.tw. or elbow/ (33336)  
 16 14 and 15 (2860)  
 17 13 or 16 (4114)  
 18 12 and 17 (138)  
 19 remove duplicates from 18 (137)

## Appendix 5. AMED (OvidSP) search strategy

Database: AMED (Allied and Complementary Medicine) <1985 to May 2016>

Search Strategy:

-----  
 1 Randomized controlled trials/ (1780)  
 2 Random allocation/ (313)  
 3 Double blind method/ (585)  
 4 Single-Blind Method/ (75)  
 5 exp Clinical Trials/ (3543)  
 6 (clin\$ adj25 trial\$).tw. (6397)  
 7 ((singl\$ or doubl\$ or treb\$ or trip\$) adj25 (blind\$ or mask\$ or dummy)).tw. (2664)  
 8 placebos/ (571)  
 9 placebo\$.tw. (2887)  
 10 random\$.tw. (15869)  
 11 research design/ (1847)  
 12 Prospective Studies/ (898)  
 13 meta analysis/ (175)  
 14 (meta?analys\$ or systematic review\$).tw. (2852)  
 15 control\$.tw. (32646)  
 16 (multicenter or multicentre).tw. (916)  
 17 ((study or studies or design\$) adj25 (factorial or prospective or intervention or crossover or cross-over or quasi-experiment\$)).tw. (11738)  
 18 or/12-17 (41971)  
 19 Cubital Tunnel Syndrome/ or (Cubital Tunnel adj5 Syndrome).tw. (11)  
 20 ulnar neuropath\$.mp. or ulnar nerve/ or ulnar nerve.tw. or nerve compression syndromes/ (381)  
 21 elbow.tw. or elbow/ (1959)  
 22 20 and 21 (65)  
 23 19 or 22 (71)  
 24 18 and 23 (15)  
 25 remove duplicates from 24 (15)

## Appendix 6. LILACS search strategy

((((MH:C10.668.829.500.850\$ or “ulnar neuropathy” or “ulnar neuropathies” or “neuropatias cubitale” or “neuropatias ulnares” or “ulnar nerve” or “nervo ulnar”) and (elbow or elbows or codo or cotovelo)) or (“cubital tunnel syndrome” or “síndrome del tunel cubital” or “síndrome do tunel ulnar”)) and ((PT:“Randomized Controlled Trial” or “Randomized Controlled trial” or “Ensayo Clínico Controlado Aleatorio” or “Ensaio Clínico Controlado Aleatório” or PT:“Controlled Clinical Trial” or “Ensayo Clínico Controlado” or “Ensaio Clínico Controlado” or “Random allocation” or “Distribución Aleatoria” or “Distribuição Aleatória” or random\$ or Randomized or randomly or “double blind” or “duplo-cego” or “duplo-cego” or “single blind” or “simples-cego” or “simples cego” or placebo\$ or trial or groups) AND NOT (B01.050\$ AND NOT (humans or humanos or humanos))))

## Appendix 7. EBSCOhost CINAHL search strategy

Monday, June 06, 2016 11:01:44 AM

S30 S28 AND S29 8  
S29 EM 20141014- 577,335  
S28 S18 and S27 74  
S27 S25 and S26 312  
S26 MH elbow or ti elbow or ab elbow 3,585  
S25 S19 or S20 or S21 or S22 or S23 or S24 2,330  
S24 nerve compression n5 syndrome\* 1,487  
S23 (MH “Nerve Compression Syndromes”) 1,401  
S22 cubital tunnel n5 syndrome\* 119  
S21 ulnar neuropath\* 279  
S20 ti (ulnar nerve\*) or ab (ulnar nerve\*) 298  
S19 (MH “Ulnar Nerve”) 809  
S18 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 836,818  
S17 ABAB design\* 91  
S16 TI random\* or AB random\* 173,912  
S15 ( TI (cross?over or placebo\* or control\* or factorial or sham? or dummy) ) or ( AB (cross?over or placebo\* or control\* or factorial or sham? or dummy) ) 345,985  
S14 ( TI (clin\* or intervention\* or compar\* or experiment\* or preventive or therapeutic) or AB (clin\* or intervention\* or compar\* or experiment\* or preventive or therapeutic) ) and ( TI (trial\*) or AB (trial\*) ) 125,186  
S13 ( TI (meta?analys\* or systematic review\*) ) or ( AB (meta?analys\* or systematic review\*) ) 46,385  
S12 ( TI (single\* or doubl\* or tripl\* or trebl\*) or AB (single\* or doubl\* or tripl\* or trebl\*) ) and ( TI (blind\* or mask\*) or AB (blind\* or mask\*) ) 26,841  
S11 PT (“clinical trial” or “systematic review”) 132,020  
S10 (MH “Factorial Design”) 972  
S9 (MH “Concurrent Prospective Studies”) or (MH “Prospective Studies”) 282,840  
S8 (MH “Meta Analysis”) 24,634  
S7 (MH “Solomon Four-Group Design”) or (MH “Static Group Comparison”) 49  
S6 (MH “Quasi-Experimental Studies”) 7,850  
S5 (MH “Placebos”) 9,729  
S4 (MH “Double-Blind Studies”) or (MH “Triple-Blind Studies”) 33,490  
S3 (MH “Clinical Trials+”) 198,849  
S2 (MH “Crossover Design”) 13,769  
S1 (MH “Random Assignment”) or (MH “Random Sample”) or (MH “Simple Random Sample”) or (MH “Stratified Random Sample”) or (MH “Systematic Random Sample”) 72,718

## Appendix 8. PEDro search strategy

Simple search: “cubital tunnel syndrome”, “ulnar neuropathy”

Advanced search

Abstract and Title: “cubital tunnel syndrome” OR “ulnar neuropathy elbow”

## Appendix 9. ClinicalTrials.gov search strategy

Simple search: “ulnar nerve”

## Appendix 10. World Health Organization International Clinical Trials Registry Platform search strategy

Simple search: “ulnar nerve”

## WHAT'S NEW

Date	Event	Description
8 May 2016	New citation required and conclusions have changed	Three trials added.
8 May 2016	New search has been performed	Searches were updated to 31 May 2016.

## HISTORY

Protocol first published: Issue 4, 2007

Review first published: Issue 2, 2011

Date	Event	Description
10 April 2012	New citation required but conclusions have not changed	Searches were updated to 20 February 2012. No new trials found, but one excluded study added
10 July 2011	New search has been performed	Reporting of results in the abstract revised. Minor edits throughout

## CONTRIBUTIONS OF AUTHORS

Pietro Caliandro: protocol development, searching for trials, quality assessment of trials, data extraction, data analyses, development of final review.

Giuseppe La Torre: protocol development (statistical analysis), searching for trials, quality assessment of trials, data extraction, data analyses.

Roberto Padua: protocol development, searching for trials, quality assessment of trials, data extraction, data analyses, development of final review.

Fabio Giannini: protocol development, searching for trials, quality assessment of trials, data extraction, data analyses, development of final review.

Luca Padua: protocol development, searching for trials, quality assessment of trials, data extraction, data input, data analyses, development of final review; corresponding author.

## DECLARATIONS OF INTEREST

PC: none known

GLT: none known

RP: none known

FG: none known

LP: none known

## SOURCES OF SUPPORT

### Internal sources

- Don Gnocci Foundation, via Maresciallo Caviglia n.30, Rome 00194, Italy.

### External sources

- No sources of support supplied

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We used updated 'Risk of bias' methodology as described in the *Cochrane Handbook for Systematic Reviews of Interventions* and included 'Summary of findings' tables ([Higgins 2011](#)).

We collected the information on concomitant treatments and the additional information listed under 'Other data' in the [Methods](#).

Data did not allow authors to perform subgroup analyses.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Decompression, Surgical [methods]; Elbow; Exercise Therapy [methods]; Nerve Transfer [methods]; Patient Education as Topic [methods]; Randomized Controlled Trials as Topic; Splints; Ulna [surgery]; Ulnar Nerve [\*surgery]; Ulnar Nerve Compression Syndromes [surgery; \*therapy]

### MeSH check words

Humans