# A multicentre, randomized controlled trial of neurolysis for mild ulnar neuropathy at the elbow

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Primary objective:The primary objective of this study is to compare the short-term and long-term efficacy of neurolysis and a conservative strategy for relieving symptoms in mild cases of UNE. Secondary objectives:- VAS score for paresthesias- VAS...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Peripheral neuropathies |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34554

**Source**
ToetsingOnline

**Brief title**
effect of neurolysis for mild ulnar neuropathy at the elbow

### Condition

- Peripheral neuropathies

**Synonym**
nerve at elbow, ulnar neuropathy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Elisabeth Ziekenhuis
**Source(s) of monetary or material Support:** geen

## Intervention

**Keyword:** neurolysis, treatment, ulnar neuropathy at the elbow

## Outcome measures

**Primary outcome**

5.1.1 Main study parameter

A. To evaluate the outcome patients will be asked to score the treatment result on a 6-point ordinal transition scale, which is subsequently dichotomized as 'improved' (*completely recovered* or *much improved*) and 'not improved' (*slightly improved*, *no change*, *slightly worse*, *much worse*).

The scores at 3 months will be used to evaluate short time effects and the score after 12 months will be used to evaluate long term effects

**Secondary outcome**

5.1.2 Secondary study parameters

- VAS score for paresthesias
- VAS score for pain at the hand
- VAS score for numbness
- Frequency of complications in the operated group
- Number of patients that drop out in the conservative group because they needed surgery
- Socio-economic parameters: work situation; sick leave, change in work/adapted function at work
- Functional scales

# Study description

### Background summary

Ulnar neuropathy at the elbow (UNE) is the second most common entrapment neuropathy and is frequently encountered in general practice. There is no international consensus for the treatment of ulnar neuropathy at the elbow (UNE). The management of UNE varies from non-operative measures to surgery. Especially in mild cases with purely sensory signs, a trial of conservative treatment is usually advocated. It is not clear at what stage patients with UNE should be operated. Patients with moderate to severe muscle weakness of the by the ulnar nerve innervated muscles and the patients who develop progressive muscle weakness are usually referred for surgery. This contrasts with common practice in patients with CTS who are often operated, even when neurological examination is normal and nerve conduction studies show only minor abnormalities. We demonstrated that patients with purely sensory signs of UNE do not necessarily represent the less severe (or benign) side of the spectrum of UNE, because 45% of the patients with purely sensory signs had electromyographic abnormalities indicating injury of motor axons. At present there are no randomized studies that compared surgery with conservative treatment measures in patients with mild UNE. Most studies on the effect of surgery in UNE compare different surgical techniques (3). In a non-randomized study with a relative small number of patients with mild to severe UNE we found an advantage of surgery over conservative treatment; 35% of the conservative group showing a good outcome versus 61% in the operated group. Bartels et al reported a good outcome after surgery in 48% of the patients. Therefore a clinical randomized trial is warranted to evaluate the effect of surgery in patients with mild UNE.

### Study objective

Primary objective:
The primary objective of this study is to compare the short-term and long-term efficacy of neurolysis and a conservative strategy for relieving symptoms in mild cases of UNE.

Secondary objectives:
- VAS score for paresthesias
- VAS score for pain at the hand
- VAS score for numbness
- Frequency of adverse events ascribed to the therapy (e.g. surgery complications in the operated group)
- Number of patients that drop out because they needed surgery
- Socio-economic parameters: work situation; sick leave, change in work / adapted function at work

- Functional scales: SF-36 and McGill Pain questionnaire

## Study design

A randomized controlled multi-center trial with two arms: neurolysis and conservative treatment.

## Intervention

4.1 Surgical treatment
Surgical treatment of ulnar neuropathy will be simple decompression. In this procedure a 6 to 8 cm curvilinear incision is made, overlying the course of the ulnar nerve as it traverses the elbow lateral to the medial epicondyle. The deep fascia overlying the nerve is divided and the nerve is followed distally into the postcondylar groove. The roof of the cubital tunnel is formed by the cubital tunnel retinaculum or arcuate ligament. This fascial roof between the medial epicondyle and olecranon is divided in a proximal to distal direction (5) If (sub)luxation of the ulnar nerve is observed during surgery an anterior transposition procedure may be performed by the operating neurosurgeon. The presence of (sub)luxation will be established by flexing the elbow after division of the arcuate ligament. Luxation is present when the ulnar nerve moves anteriorly out of the sulcus into the space in front of the medial epicondyle. Subluxation is present when there is anterior displacement of the ulnar nerve out of its bed, but the nerve remains posterior to the medial epicondyle (3). The findings during surgery will be recorded and if there are signs of compression, the level of compression will be measured from the center of the medial epicondyle. After surgery patients are encouraged to use their arm as soon as possible.

5.2 Conservative treatment
Conservative treatment consists of written instructions involving posture of the afflicted elbow. A splint will not be prescribed. The instructions are the following. Try to minimize elbow flexion and keeping the elbow extended as much as possible. Avoid repetitive elbow flexion and extension or direct pressure on the elbow. Patients are advised to avoid crossing their arms when sitting, and to rest the arm supinated on the thigh. The telephone should be held in the other hand, with excessive reading a book stand is advised. At work a pillow should be placed beneath the elbow on the desk, and keyboard height and angle should be adjusted. Patients are allowed to take analgetic medication.

## Study burden and risks

Patients will have to visit the outpatient clinic 4 times (baseline visit and three follow-up visits), which is one to two times more than is usual for patients with this diagnosis. At these visits three questionnaires have to be

filled in, and patients will undergo a short physical examination, which is standard procedure. They will undergo electrophysiological examinations once, these are standard diagnostic tests for every patient with UNE. The surgical procedure that will be performed in half of the patients is a standard operating procedure for treating UNE.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

a. Age 18 years or more.
b. Clinical signs of an ulnar neuropathy (i.e., pain, numbness or paraesthesias in the area of the ulnar nerve, weakness or clumsiness of ulnar muscles).
c. Duration of symptoms < 9 months.
d. MRC sumscore of the flexor carpi ulnaris (FCU), flexor digitorum profundus digiti IV + V

(FDP IV-V), abductor digiti minimi (ADM) and first dorsal interosseous I (FDI) muscles > 16 (of a maximum score of 4 x 5 = 20).
e. Electrophysiological * or sonographic ** evidence of localization of the lesion at the elbow.
f. Informed written consent.

### Exclusion criteria

a. evidence of a coexistent polyneuropathy.
b. History of hereditary neuropathy with liability to pressure palsies
c. Traumatic origin of UNE.
d. Malignancy.
e. Previous or current use of chemotherapy.
f. Unable to follow up

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Treatment

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-10-2006 |
| Enrollment: | 120 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 15-08-2006 |
| Application type: | First submission |

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|---|---|
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 02-11-2009 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 27989
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL12591.008.06 |