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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27989

Source
Nationaal Trial Register

Brief title
DUNE study: neurolysis for mild UNE

Health condition

ulnar neuropathy, neurolysis, conservative treatment

ulnaropathie, neurolyse, conservatief beleid

Sponsors and support

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Source(s) of monetary or material Support: none,
fund=initiator

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary objectives:

1. VAS score for paresthesias;

2. VAS score for pain at the hand;

3. VAS score for numbness;

4. Frequency of adverse events ascribed to the therapy (e.g. surgery complications in the operated group);

5. Number of patients that drop out because they needed surgery;

6. Socio-economic parameters: work situation; sick leave, change in work / adapted function at work;

7. Functional scales: SF-36 and McGill Pain questionnaire.

Study description

Background summary

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

Background of the study:
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.

Objective of the study:
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.

Study population:
All patients, 18 years and older with a mild ulnar neuropathy at the elbow visiting the departments of neurology of five large general teaching hospitals (Atrium Medical Centre in Heerlen, St. Elisabeth Hospital in Tilburg, Canisius Wilhelmina Hospital in Nijmegen, Lucas Andreas Hospital Amsterdam, and Medisch Spectrum Twente, Enschede) can enter the study.

Mild UNE is defined as 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) and a 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) with electrophysiological or sonographic evidence of localization of the lesion at the elbow.

One hundred twenty evaluable patients will be included into the study. Each patient entered into the study must receive the allotted course of treatment and complete the required activities specified in this protocol. Under no circumstances will patients who enroll in this study and who drop out for any reason, be permitted to re-enroll for a second course of treatment.

Because ulnar neuropathy is the second most common entrapment neuropathy in the arm with an estimated mean annual incidence of 25 per 100,000 person-years, we expect 300 referrals a year in the five hospitals together. Of these referrals we expect 120 patients to meet the inclusion criteria. So, it is expected that it takes 1.4 years to include 120 patients The diagnosis of ulnar neuropathy at the elbow will be based on the clinical findings, electrodiagnostic studies or sonographic studies. Half of the patients meeting the inclusion criteria will be prospectively randomized for surgery, the other half will be randomized for conservative treatment. All subjects must give written informed consent before entering the study.
Intervention (if applicable):
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.

Primary study parameters/outcome of the study:
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

Secundary study parameters/outcome of the study (if applicable):
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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
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.

Study objective

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). At present there are no randomized studies that compared surgery with conservative treatment measures in patients with mild UNE. 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 Therefore a clinical randomized trial is warranted to evaluate the effect of surgery in patients with mild UNE.

Intervention

neurolysis of the ulnar nerve at the elbow: simple decompression

control: no intervention, conservative treatment

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 years or more;

2. 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);

3. Duration of symptoms < 9 months;

4. 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);

5. Electrophysiological * or sonographic ** evidence of localization of the lesion at the elbow;

6. Informed written consent.

Exclusion criteria

1. Evidence of a coexistent polyneuropathy;

2. History of hereditary neuropathy with liability to pressure palsies;

3. Traumatic origin of UNE;

4. Malignancy;

5. Previous or current use of chemotherapy;

6. Diabetes mellitus;

7. Alcoholism (>5 daily);

8. Inoperability;

9. Ulnar release ipsilaterally in the past;

10. Involved in law suit/legal procedures concerning the ulnar neuropathy;

11. Unable to follow up.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2006
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-09-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34554
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1018
NTR-old	NTR1049
CCMO	NL12591.008.06
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON34554

Study results

Summary results

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