High resolution ultrasonography using a 22 MHz transducer in patients with ulnar nerve entrapment * a longitudinal study*

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To determine whether the ulnar nerve*s cross-sectional area decreases over time after endoscopic in situ neurolysis, and whether this correlates with electrophysiological findings.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON38673

Source
ToetsingOnline

Brief title
High resolution ultrasonography in UNE (HRUUNE)

Condition

- Peripheral neuropathies

Synonym
cubital tunnel syndrome, ulnar nerve compression

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: entrapment, nerve, ulnar, ultrasonography

Outcome measures

Primary outcome

The main study parameter is the cross-sectional area (CSA) of the ulnar nerve,

measured at 6 different locations in the arm, measured preoperatively and in

the course of time after surgery.

Secondary outcome

- CSA ratio

- Nerve conduction velocity

- Thickness m. interossei dorsalis I

- Length of swelling

- Microstructure variables

- Arm/hand function

Study description

Background summary

Ulnar nerve entrapment (UNE) is the most common neuropathy after carpal tunnel syndrome. It can be diagnosed by a combination of clinical and electrophysiological findings. Electrophysiological tests give some information about the location of the entrapment, but it does not provide information about the exact location. Ultrasonography might provide this, by making the location of entrapment visible, because the nerve shows an increased cross-sectional area proximal to the entrapment site. Knowing the exact location of the entrapment is essential, because opening the cubital tunnel during surgery without knowing the exact location could miss the place of entrapment. Next to that, long term follow-up with ultrasonography can provide information about the state of the recovery of the nerve, in terms of recurrent or persisting disease. Given the improved high resolution ultrasound (HRU) devices, more

precise and detailed information could be obtained.

Study objective

To determine whether the ulnar nerve*s cross-sectional area decreases over time after endoscopic in situ neurolysis, and whether this correlates with electrophysiological findings.

Study design

This is a descriptive study with a longitudinal study design.

Study burden and risks

Patients who participate in this study will receive three additional ultrasonographies, one additional electrophysiological test, and one additional clinical examination. The patients are asked to fill out a questionnaire to assess hand function during every visit. These measurements and research acts will be performed during the hospital visits that are part of the standard treatment protocol. Patients will be asked to bring one additional visit to the hospital that is not part of the treatment protocol. Because participation in this study has no consequences for the surgical treatment that patients receive, this study has no benefits for the participating patients. The benefit lies potentially in future UNE patient groups. The ultrasonographies will not be harmful, because no contrast agents will be used, and no sensitive organs or embryo*s are visualized. One additional electrophysiological test will be performed. The electrophysiological examinations can be unpleasant, but there are no risks associated with the tests. This study is group-related as it is evident that observations on the ulnar nerve after ulnar nerve release, only can be performed in UNE patients.

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

- adults of 18 years of age or older
- those diagnosed with ulnar nerve entrapment who received an indication for surgery
- decisionally capacitated
- written informed consent

Exclusion criteria

- (history of) generalized neuropathy
- (history of) polyneuropathy
- earlier ulnar entrapment neuropathy
- afunctional ulnar nerve
- patient is unlikely to complete follow-up (e.g. relocation)
- patient has a pace maker
- BMI > 30

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 25209
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43057.042.13
OMON	NL-OMON25209