Hoge resolutie echografie bij patiënten met beknelling van de elleboogzenuw - een longitudinaal onderzoek

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25209

Source
Nationaal Trial Register

Brief title
HRUUNE

Health condition

ulnar nerve entrapment

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

- Cross-sectional area (CSA) of the ulnar nerve

Secondary outcome

- CSA ratio of upperarm - forearm

- nerve conduction velocity

- thickness of m. interosseus dorsalis I

- patient perceived arm/hand function

Study description

Background summary

Rationale: 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 rough 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.
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 population: Adults (≥ 18 years of age) with ulnar nerve entrapment will be included in this study. Those with a history of polyneuropathy, current polyneuropathy, and earlier ulnar entrapment neuropathy will be excluded. In addition, patients with an afunctional ulnar nerve, without a chance of functional recovery, will be excluded, as well as patients who are unlikely to complete the follow-up measurements (e.g. due to relocation).
Main study parameters/endpoints: 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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

We expect that the increased cross-sectional area of the ulnar nerve proximal to the entrapment site, will decrease after endoscopic in situ neurolysis. Additionally, we expect that this decrease will correlate to the electrophysiological findings in the course of time.

Study design

- Preoperatively

- 2 weeks postoperatively

- 3 months postoperatively

- 6 months postoperatively

- 12 months postoperatively

Intervention

None. This is an observational, longitudinal study, in which one group of patients will have a follow up until 1 year postoperative. The standard treatment protocol does not change because of their participation. The only difference is that the participating patients will bring more visits to the hospital than non-participating patients, because of the follow-up measurements.

Contacts

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Eligibility criteria

Inclusion criteria

- adults >= 18 years of age;

- written informed consent;

- decisional capacitated.

Exclusion criteria

- (history of) generalized neuropathy

- (history of) polyneuropathy

- earlier ulnar nerve entrapment neuropathy

- afunctional ulnar nerve

- patient is unlikely to complete follow-up measurements (e.g. due to relocation)

- Body Mass Index > 30

- pace maker

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-05-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38673
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3825
NTR-old	NTR4007
CCMO	NL43057.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON38673

Study results

Summary results
N/A