Ulnar neuropathy at the elbow: shortterm follow-up using clinical, electrodiagnostic and sonographic data

Published: 12-05-2010 Last updated: 03-05-2024

Assess the natural course of UNE in patients with mild to moderate symptoms by using clinical, electrophysiological and ultrasonographic data

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typePeripheral neuropathiesStudy typeObservational invasive

Summary

ID

NL-OMON34938

Source

ToetsingOnline

Brief title

Follow-up in ulnar neuropathy at the elbow

Condition

Peripheral neuropathies

Synonym

Ulnaropathy; nerve entrapment at the elbow

Research involving

Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: afdeling neurologie/klinische neurofysiologie

HagaZiekenhuis

Intervention

Keyword: Electromyography, Follow-up, Ulnar neuropathy, Ultrasonography

Outcome measures

Primary outcome

Differences over time in the results of electrodiagnostic and sonographic

studies

Secondary outcome

Not applicable

Study description

Background summary

Ulnar neuropathy at the elbow (UNE) is considered the second most common entrapment neuropathy. Diagnosis of UNE is made on clinical and electrophysiological examination. Ultrasound of the ulnar nerve is becoming more available and has been validated in recent years. There is no gold standard in the treatment of UNE.

It is well known that mild to moderate cases of UNE, i.e. with solely sensory symptoms and sensory plus mild motor symptoms respectively, improve over time with lifestyle changes. Though abovementioned techniques have established their part in diagnosing UNE, no prospective study yet focused on possible short-term changes and differences in electrophysiologic and ultrasonographic studies to monitor the disease or decision making regarding treatment.

Study objective

Assess the natural course of UNE in patients with mild to moderate symptoms by using clinical, electrophysiological and ultrasonographic data

Study design

Prospective cohort study

Study burden and risks

The first ultrasound and the second visit with all three examinations is the extra burden for the patients. This extra burden mainly applies to those patients with improvement of their complaints, since in clinical practice most patients will receive a second EMG and/or additional ultrasonographic examination with deterioration of their symptoms.

Contacts

Public

HagaZiekenhuis

Leyweg 275 2545 CH Den Haag NL

Scientific

HagaZiekenhuis

Leyweg 275 2545 CH Den Haag NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Clinically suspect ulnar neuropathy at the elbow

Exclusion criteria

Anatomical abnormalities near the elbow, including mass lesions and acute penetrating traumatic lesions

Previous ulnar nerve or elbow surgery

Pregnancy

Paresis of ulnar-innervated intrinsic hand muscles on the Medical Research Council (MRC)

scale of 3 or lower

Being unable to understand or read the Dutch language

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-05-2010

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 12-05-2010

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register ID

CCMO NL31928.098.10