Follow-up of carpal tunnel syndrome

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

Summary

ID

NL-OMON43084

Source
ToetsingOnline

Brief title
Follow-up of CTS

Condition

- Peripheral neuropathies

Synonym
carpal tunnel syndrome, CTS

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: niet;vindt plaats in vrije tijd

Intervention

Keyword: carpal tunnel syndrome follow-up

Outcome measures

Primary outcome

We examine the amount that CTS symptoms have changed over the years on the basis of Symptom Severity Score (SSS) and the Functional Status Score (FSS), commonly known as the Boston Carpal Tunnel Questionnaire (BCTQ). In addition, we compare the NCS characteristics and the cross-sectional area (CSA) in some patients.

Secondary outcome

NCS characteristics (nerve conduction velocity, latency times, distal motor latency)

Cross-sectional area, measured by using the ellips method and the continuous trace method.

Study description

Background summary

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy and causes complaints such as paresthesias in the area of the median nerve, pain and loss of strength in the hand. Diagnosis is based on clinical features and can be confirmed by nerve conduction studies (NCS) and Ultrasonography (US). Pregnancy is one of the major risk factors. If the diagnosis is made, patients may undergo a surgical procedure in which a release of the median nerve at the carpal tunnel takes place. Little is known about long term effects of this treatment due to lack of adequate follow-up of these patients after surgery.

Study objective

We aim to investigate the amount of patients who have lasting benefit from such surgery, and which proportion eventually get recurrent symptoms. We are going to investigate the cohort which has previously been studied by our group (protocol Dr. Claes F). In addition, we study the NCS characteristics to find

out if they are predictive for success or failure of surgery, so that we can identify those patients, who will be expected to benefit from an intervention. Patients who have recurrent symptoms, will be subjected to another NCS and US in order to compare it with the pre-operative findings, to identify predictors for recurrence of symptoms. Some of the patients that have been operated successfully will be asked as control. Besides, we would like study patients with CTS during a previous pregnancy, for recurrent symptoms after birth and for the necessity of surgery.

Study design

Prospective cohort study

Study burden and risks

Using non-invasive and non-painful procedures, we attempt to find out if we are able to predict outcome after a median nerve release in patients with CTS. In addition, we will investigate the profit of a shorter NCS procedure, which could be possible if a certain value is very predictive for recovery or even no recovery after surgery.
The advantage could be that this non-invasive -but for some people annoying- NCS could be reduced in the future as well as that we can discourage surgery in patients in which we know in advance that the recovery won't be sufficiently. In addition, we hope find evidence to the natural course of a CTS. Moreover, we want to figure out whether we have to treat patients with carpal tunnel syndrome during pregnancy, or that the symptoms after a pregnancy will disappear again.

In conclusion: There is a low risk (no side effects, no invasive procedure and low load for the patient (only one hospital visit), and once completing questionnaires during 5a 10 minutes. There are no further precepts or restrictions.

Contacts

Public
Canisius Wilhelmina Ziekenhuis

Weg door Jonkerbos 100
Nijmegen 6532 SZ
NL
Scientific
Canisius Wilhelmina Ziekenhuis

Weg door Jonkerbos 100
Nijmegen 6532 SZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients who fulfilled CTS criteria mentioned below*. Also patients who indicate that the fifth finger is also involved.;* patients with pain and/or paresthesia in and restricted to the sensory distribution of the median nerve for at least 3 months, and if patients met 2 or more of the following criteria: (1) nocturnal pares- thesias, (2) reproduction or aggravation of paresthesias or pain by provocative tests (Tinel or Phalen*s sign), (3) aggravation of paresthesias by activities such as car driv- ing, bicycling, holding a book, or holding a telephone, and (4) relieve of symptoms by shaking the hand (Flick sign)

Exclusion criteria

clinical signs of polyneuropathy or known hereditary polyneuropathy, history of hand trauma,previous surgery for CTS, every atrophy of m. pollicis breves, history of rheumatoid arthritis, arthritis of the wrist, diabetes mellitus, hypothyroidism or hyperthyroidism, alcoholism.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2017
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	31-07-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL59236.091.16