The carpal tunnel syndrome. Clinical definite CTS with normal electrodiagnostic studies and diagnostic value sonography.

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A: The purpose of the current trial is to investigate what is the best treatment for patients with clinical definite CTS and normal nerve conduction studies and to see what is the value of ultrasonography in this specific group of patients.B: The...

Ethical review	Approved WMO
Status	Pending
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON29793

Source
ToetsingOnline

Brief title
The carpal tunnel syndrome.

Condition

- Peripheral neuropathies

Synonym
tunnelsyndrome

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis

Source(s) of monetary or material Support: Er is geen sprake van specifieke externe financiering

Intervention

Keyword: carpal tunnel syndroom, CTS, electrodiagnostic, sonography

Outcome measures

Primary outcome

A: Primairy outcome measure: the percentage of patients with no complaints

after 6 months.

B: Primairy outcome measure: the percentage of patients with clinical definite

and probable CTS with ultrasonography meeting the criteria of CTS.

Secondary outcome

A: Secundairy outcome measures:

1. The percentage of patients with an improvement of the Functional Status

Score with 40 % or more after 6 months.

2. The percentage of patients in group 2 who are operated on after 6 months.

3. The percentage of patients in group 1 with persistent complaints of CTS.

4. The percentage of patients with ultrasonography meeting the criteria of CTS.

B: Secundairy outcome measure:

The correlation between nerve conduction studies and ultrasonography in

patients with clinical definite and probable CTS.

Study description

Background summary

A: The carpal tunnel syndrome is a common entrapment neuropathy and is an important cause of functional disability. Depending on the severity of complaints a conservative or surgical treatment is chosen. 8 To 13 % of patients have a normal electrodiagnostic investigation. There is no consensus about the treatment in this specific group of patients. Because of this, treatment varies with different neurologists of neurosurgeons. Ultrasonography of nerves has improved significantly in the last few years.

B: The carpal tunnel syndrome is a common entrapment neuropathy and is an important cause of functional disability. Depending on the severity of complaints a conservative or surgical treatment is chosen. In nearly all patients an elctrodiagnostic examination is done to confirm the diagnosis. In many patients however, the complaints are very clear and in these cases the question rises if such an examination is really necessary. In the past few years the technique of ultrasonography of nerves has been extensively improved and can possibly replace an electrodiagnostic examination in the future.

Study objective

A: The purpose of the current trial is to investigate what is the best treatment for patients with clinical definite CTS and normal nerve conduction studies and to see what is the value of ultrasonography in this specific group of patients.

B: The purpose of this trial is to investigate the value of sonography in patients with clinical definite or probable CTS.

Study design

A: Patients with clinical definite CTS, who meet the inclusion- and exclusioncriteria, with normal nerve conductionstudies are randomised into two groups. Group 1 will be treated surgically, group 2 will treated conservatively. Because of the expected higher succesrate in the surgically treated group, there will be 2 patients included in the surgery group for every patient in the conservative group. After 6 months there wil be a clinical follow up and the results are compared, with the primary outcome being the percentage of patients with no complaints. Also the percentage of positive sonography examination will be determined.

B: Patients will be devided into two groups according to clear clinical criteria: group 1 with clinical definite CTS and group 2 with clinical probable

CTS. All patients undergo a standardised nerve conduction study and ultrasonography of the carpal tunnel, measuring the crossectional area of the median nerve. The treatment will be determined by the patients own neurologist in agreement with the patient.

Intervention

A: Patients in group 1 will be treated surgically with open release of the carpal tunnel. The operation is carried out by a neurosurgeon. Patients in group 2 are treated conservatively.

B: There is no specific intervention because of this trial. Patients will be treated by their own neurologist as in daily clinical practice.

Study burden and risks

A: Patients undergo a non-invasive ultrasonography of the carpal tunnel. There are strict clinical criteria to prevent patients being operated unnecessary. Follow up studies have indicated that up to a third of patients with a CTS can improve spontaneously after a follow up of maximum 11 years. With this in mind a wait and see policy during 6 months is justified.

B: Patients undergo a non-invasive ultrasonography of the carpal tunnel, next to a nerve conduction study which is carried out always in daily clinical practice. There are no risks involved with the ultrasonography examination. The examinations will be carried out on the same day as much as possible. Patients are seen in follow up after 6 months in the neurology outpatient department.

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

Paresthesia or pain in de area supplied by median nerve, with at least 2 of the following: nocturnal complaints, improvement by Flick's sign, worsening with handmovements.
Normal electrodiagnostic investigation of the median nerve.

Exclusion criteria

Clinical polyneuropathy, Trauma, bad general condition with reduced life expectancy, severe atrophy of m. Abductor pollicis brevis, pregnancy, alcoholism,
arthritis of arthrosis, known diabetes mellitus, reumatoid arthritis, thyroid pathology, HNLPP, languagebarrier, psychiatric problem, other neurological problems in arm, former surgery, refusal surgery, age younger than 18, participance in other trials

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

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	NL11391.091.06