The Dutch Injection versus Surgery TRIal in Carpal Tunnel Syndrome patients

Published: 15-09-2017
Last updated: 19-08-2024

The objective of this study is to assess the efficacy and cost-effectiveness of a treatment strategy starting with surgical intervention compared to a starting treatment with steroid injection.

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

Summary

ID

NL-OMON55537

Source
ToetsingOnline

Brief title
DISTRICTS

Condition

- Peripheral neuropathies

Synonym
Carpal tunnel syndrom; nerve compression at the wrist

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw;Zorgverzekeraars Nederland;Federatie Medisch Specialisten

Intervention

Keyword: carpal tunnel syndrome, steroid injection, surgical intervention

Outcome measures

Primary outcome

if the treatment strategy starting with a surgical intervention results in a

higher recovery rate at 18 months follow-up compared to starting treatment with

a steroid injection.

Secondary outcome

A) time to recovery during 18 months of follow-up;

B) number of patients recovered at different time points during follow-up;

C) level of symptom severity at different time points during follow-up;

D) hand functioning at 18 months follow-up;

E) patient*s global perception of recovery at 18 months;

F) patient satisfaction at 18 months;

G) quality of life at 18 months;

H) number of additional treatments during follow-up;

I) number of adverse events during follow-up;

J) use of care and health-related costs during follow-up.

Study description

Background summary

Carpal tunnel syndrome (CTS) is the most common peripheral neuropathy and is characterized by pain, paresthesia, numbness, and weakness of the affected hand. The cause of CTS is entrapment of the median nerve at the wrist. There are no universally accepted criteria for diagnosing CTS. Electrodiagnostic

testing (EMG) and sonography are both accurate tools to confirm the diagnosis. The overall prevalence rate of electrophysiological confirmed CTS in the Netherlands is 9.2% in women and 0.6% in men. There are approximately 300,000 patients with CTS in the Netherlands. Estimated costs for absenteeism due to CTS are 26,5 million euro/year. Treatment options for CTS include splinting, steroid injections, and surgical decompression.

A systemic review suggested that surgical intervention is more effective than non-surgical intervention for relieving symptoms of CTS. However, most neurologists initiate treatment with steroid injections because they consider this very easy to perform and relatively safe. Consequently, patients with mild to moderate CTS are often treated first with one or two steroid injections. If symptoms remain or reoccur, patients are referred for surgical intervention. Because of the high frequency of persisting or reoccurring symptoms, this strategy may result in an postponement of the more effective treatment, that is, surgical intervention, which could lead to unnecessary health loss, work absenteeism, and costs. Patients with severe CTS are often primarily treated surgically, though the best treatment strategy is also not known.

The lack of comparative knowledge regarding the best treatment strategy for CTS, that is, starting with a surgical intervention or starting treatment with a steroid injection is reflected in the concept CBO-guideline for CTS (2016), which states no preference for one of the strategies. All of the above contributes to the considerable practice variation in the treatment of CTS.

Study objective

The objective of this study is to assess the efficacy and cost-effectiveness of a treatment strategy starting with surgical intervention compared to a starting treatment with steroid injection.

Study design

The study is a multicenter open-label randomized controlled trial. The inclusion period will be 18 months. The follow-up of each patient is 18 months from randomization. The approximately 30 participating centers will be recruited from university medical centers, STZ -hospitals (Stichting Topklinische Ziekenhuizen), general hospitals, and ZBC*s (Zelfstandig behandelcentra) in the Netherlands.

Intervention

Patients will be randomly assigned to two treatment strategies. One strategy consists of starting with a steroid injection proximal to the carpal tunnel (injection group). The other strategy consists of starting with a surgical intervention (surgery group). If needed, these treatments can be followed by

additional treatments such as a second injection or surgical intervention. Independent of the initial treatment performed, patients will receive the usual care at the discretion of their physician.

Study burden and risks

Both surgical intervention as well as steroid injections for the treatment of CTS have been widely used treatments which are in itself, not innovative and low complex, therefore patients will not be exposed to additional risks. The exclusion criteria which exclude diseases which can mimic carpal tunnel syndrome prevent patient from being submitted to a treatment which they do not need. To summarize, the risk of this trial is considered negligible.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older at time of examination;
- clinically suspected CTS;
- symptoms being present for at least 6 weeks;
- electrophysiological or sonographic confirmed CTS according to the Dutch *carpal tunnel syndrome guideline**;
- treatment within 6 weeks after inclusion.
- the patient can only be included for the treatment of one hand if both hands are eligible; this will be the hand with the most severe complaints or the dominant hand if both hands are equally affected.
- surgery and injection are both considered as potential treatments for the CTS related symptoms**., * There is no consensus about findings with sonography in CTS. The current opinion of the DUTCH CTS study group is that a CSA of more than 11 mm2 is abnormal and thus confirms a clinical suspicion of CTS., ** Patients with secondary CTS due to a known underlying cause including, but not limited to: diabetes mellitus, rheumatoid arthritis, thyroid disease and a history of ipsilateral wrist fracture/trauma or surgery are allowed to participate in the DISTRICTS. This only if the treating physician considers both surgery and injection as effective treatments.

Exclusion criteria

- follow-up not possible;
- a previous history of surgery for CTS on the ipsilateral wrist;
- an injection for CTS in the ipsilateral wrist less than one year ago;
- previously participating in the DISTRICTS;
- clinical or neurophysiological suggestion of another diagnosis that can influence CTS, like:
- cervical radiculopathy;
- cervical myelopathy;
- brachial plexopathy including thoracic outlet syndrome;
- mononeuropathies, such as pronator teres syndrome;
- polyneuropathy, incl. Hereditary Neuropathy with Liability to Pressure Palsies;
- complex regional pain syndrome.
- unable to comprehend Dutch self-report questionnaires;
- legally incompetent adults;
- no informed consent;

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2017
Enrollment:	940
Type:	Actual

Ethics review

Approved WMO Date:	15-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL61506.018.17

Study results

Date completed:	07-06-2023

Results posted: 28-05-2024

First publication
15-05-2024