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The Dutch injection versus operation trial in carpal tunnel syndrome patients

Submission date
21/06/2017

Recruitment status
No longer recruiting

Registration date
13/07/2017

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Carpal tunnel syndrome is where pressure on a nerve in the wrist causes tingling, numbness and pain in the hand and fingers. The treatment options are surgery or steroid injection, but the best treatment strategy is not known. Evidence suggests that surgery is more effective than steroid injections for relieving symptoms. However, most neurologists start treatment with steroid injections because they consider this very easy to perform and relatively safe. Because of the high frequency of continuing or returning symptoms, this strategy may result in postponement of the more effective treatment (surgery), which could lead to unnecessary illness, absence from work, and costs. The aim of this study is to find out whether starting treatment with surgery results in a better outcome compared to starting treatment with a steroid injection.

Who can participate?
Patients aged 18 or over with carpal tunnel syndrome

What does the study involve?
Participants are randomly allocated to be treated with either surgery or steroid injection. Follow-up treatment, if necessary, is at the patient and treating physician's discretion. In the 1.5 years of follow-up there are seven timepoints where patients report their symptoms and care use using questionnaires.

What are the possible benefits and risks of participating?
A higher recovery rate, faster recovery, less care use and greater patient satisfaction is expected in the surgery group compared to the injection group. The expected result has the potential to change the current treatment strategies, not only in the Netherlands, but worldwide. Surgery and steroid injections are proven, much used, low-risk treatments. There are no additional risks, only the burden of follow-up questionnaires.

Where is the study run from?
Academisch Medisch Centrum (Netherlands)

When is the study starting and how long is it expected to run for?
December 2016 to June 2023

Who is funding the study?
1. ZonMw
2. Zorgverzekeraars Nederland

Who is the main contact?
Prof. Rob de Bie

Study website
https://www.districts.nl/

Contact information

Type(s)
Scientific

Contact name
Prof Rob de Bie

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Meibergdreef 9
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1105 AZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
837004025

Study information

Scientific Title
The Dutch injection versus operation trial in carpal tunnel syndrome patients

Acronym
DISTRICTS

Study objectives
Initial surgical intervention in patients with CTS results in a better outcome and is cost-effective when compared to initial treatment with a steroid injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
METC AMC (Medisch Ethische Toetsingscommissie Academisch Medisch Centrum), 15/09/2017, ref: 2017_171#B2017521

Study design
Multi-center open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Carpal tunnel syndrome

Interventions
Patients will be randomized using a centralized web-based application. Eligible patients will be randomized in a 1:1 ratio to the initial steroid injection or the initial surgical intervention.

The injection group starts with a single corticosteroid injection. The site of injection will be at the volar side of the forearm 3-4 cm proximal to the wrist crease between the tendons of the radial flexor muscle and the long palmar muscle. Each participating center is free in using their choice of brand and dosage of steroids, with or without local anesthetic.

The surgical group starts with a decompression of the median nerve at the carpal tunnel. Any proven surgical technique for decompression of the carpal tunnel can be used.

Follow-up treatment, if necessary, is at the patient and treating physician's discretion. In the 1.5 years of follow-up there are seven timepoints where patients report their symptoms and care use on paper self-report questionnaires.

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measures as of 26/09/2017:
Number of patients recovered, defined as having no or mild CTS symptoms as measured with the 6-item carpal tunnel symptoms scale (CTS-6), at 18 months

Previous primary outcome measures:
1. Number of patients recovered, defined as having no or mild CTS symptoms as measured with

the 6-item carpal tunnel symptoms scale (CTS-6), at 18 months
2. Time to recovery, defined as the first timepoint after the last intervention (e.g., splitting, steroid injection or surgical treatment) scoring less than 8 points if this timepoint is followed by a consecutive timepoint with a favorable outcome and no additional treatments afterwards, or if this is the last timepoint at 18 months

Secondary outcome measures
1. Time to recovery, defined as the first timepoint after the last intervention (e.g., splitting, steroid injection or surgical treatment) scoring less than 8 points if this timepoint is followed by a consecutive timepoint with a favorable outcome and no additional treatments afterwards, or if this is the last timepoint at 18 months (moved from primary outcome measures to secondary outcome measures on 26/09/2017)
2. Number of patients recovered, defined as having no or mild CTS symptoms as measured with the 6-item carpal tunnel symptoms scale (CTS-6), at 6 weeks and 3, 6, 9, 12, and 15 months
3. Level of symptom severity, measured using the CTS-6 questionnaire at 6 weeks and 3, 6, 9,12, 15, and 18 months
4. Hand functioning, measured using the QuickDASH at 18 months follow-up
5. Scar or palm pain, measured using the palmar pain scale at 6 weeks, 3, 6, 9, 12, 15 and 18 months (added 09/04/2018)
5. Patient's global perception of recovery, measured with a 7-point Likert-type item ranging from 1 (substantially deteriorated) to 7 (substantially recovered) at baseline and 18 months
6. Patient satisfaction, measured with a 7 point Likert-type item ranging from 1 (very dissatisfied) to 7 (very satisfied) at 18 months
7. Quality of life, assessed with the EuroQol (EQ-5D-5L) at 18 months
8. Number of additional treatments, defined as every treatment initiated by the neurologist after initial treatment, such as but not limited to steroid injections, (re)surgery, braces. Additional undergone treatments are determined at 6 weeks and 3, 6, 9, 12, 15, and 18 months
9. Number of adverse events, defined as the frequency, severity, nature, and duration of any adverse event throughout the course of the study. Adverse events are determined at 6 weeks and 3, 6, 9,12,15, and 18 months
10. Use of care and health-related costs during follow-up, assessed with the adapted Medical Consumption Questionnaire and the Productivity Cost Questionnaire at 3, 6, 12 and 18 months

Overall study start date
01/12/2016

Completion date
07/06/2023

Eligibility

Key inclusion criteria
1. 18 years or older at time of examination
2. Clinically suspected CTS
3. Symptoms being present for at least 6 weeks
4. Electrophysiological or sonographic confirmed CTS according to the Dutch carpal tunnel syndrome guideline
5. Treatment within 6 weeks after inclusion

Added 06/04/2018:
6. The patient can only be included for the treatment of one hand if both hands are eligible

7. Surgery and injection are both considered as potential treatments for the CTS related symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
940

Total final enrolment
941

Key exclusion criteria
Current exclusion criteria as of 06/04/2018:
1. Follow-up not possible
2. A previous history of surgery for CTS on the ipsilateral wrist
3. An injection for CTS in the ipsilateral wrist less than one year ago
4. Previously participating in the DISTRICTS
5. Clinical or neurophysiological suggestion of another diagnosis, like:
5.1. Cervical radiculopathy
5.2. Cervical myelopathy
5.3. Brachial plexopathy including thoracic outlet syndrome
5.4. Mononeuropathies, such as pronator teres syndrome
5.5. Polyneuropathy, including Hereditary Neuropathy with Liability to Pressure Palsies
5.6. Complex regional pain syndrome
6. Unable to comprehend Dutch self-report questionnaires
7. Legally incompetent adults
8. Pregnancy
9. No informed consent

Previous exclusion criteria:
1. Follow-up not possible
2. History of wrist fracture/trauma/operation
3. A previous history of injection or surgery for CTS
4. Previously participating in the DISTRICTS
5. Clinical or neurophysiological suggestion of another diagnosis that can influence CTS, like:
5.1. Cervical radiculopathy
5.2. Cervical myelopathy
5.3. Brachial plexopathy including thoracic outlet syndrome
5.4. Mononeuropathies, such as pronator teres syndrome
5.5. Polyneuropathy, including hereditary neuropathy with liability to pressure palsies
5.6. Complex regional pain syndrome

6. Secondary CTS due to known underlying cause including, but not limited to:
6.1. Thyroid disease
6.2. Rheumatoid arthritis
6.3. Diabetes mellitus
6.4. Dialysis due to kidney failure
6.5. Space-occupying lesion at the volar side of the wrist
6.6. Pregnancy
7. Known allergy to corticosteroids
8. Unable to comprehend Dutch self-report questionnaires
9. Legally incompetent adults
10. No informed consent

Date of first enrolment
07/11/2017

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Academisch Medisch Centrum
Amsterdam
Netherlands
1105 AZ Amsterdam-Zuidoost

Study participating centre
Canisius-Wilhelmina Ziekenhuis
Nijmegen
Netherlands
6532 SZ

Study participating centre
Elisabeth-TweeSteden Ziekenhuis
Tilburg
Netherlands
5022 GC

Study participating centre

Haaglanden Medisch Centrum
Den Haag
Netherlands
2512 VA

Study participating centre
OLVG Amsterdam
Amsterdam
Netherlands
1091 AC

Study participating centre
Rijnstate
Arnhem
Netherlands
6800 TA

Study participating centre
SJG Weert
Weert
Netherlands
6001 BE

Study participating centre
Zuyderland Medisch Centrum
Heerlen
Netherlands
6419 PC

Study participating centre
Catharine Ziekenhuis
Eindhoven
Netherlands
5623 EJ

Study participating centre

The Hand Clinic
Amsterdam
Netherlands
1101 GB

Study participating centre
Maasstad Ziekenhuis
Rotterdam
Netherlands
3079 DZ

Study participating centre
Ziekenhuis St Jansdal
Weert
Netherlands
6001 BE

Study participating centre
Zaans MC
Zaandam
Netherlands
1502 DV

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Alrijne Ziekenhuis
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Study participating centre

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Het LangeLand Ziekenhuis
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Netherlands
6229 HX

Study participating centre
Meander Medisch Centrum
Amersfoort
Netherlands
3813 TZ

Study participating centre
Medisch Centrum Leeuwarden
Leeuwarden
Netherlands
8934 AD

Study participating centre
Noordwest Ziekenhuisgroep
Alkmaar
Netherlands
1815 JD

Study participating centre

Radboudumc
Nijmegen
Netherlands
6525 GA

Study participating centre
Reinier de Graaf Gasthuis
Delft
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2625 AD

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Sionsberg
Dokkum
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9101 DC

Study participating centre
MC Slotervaart
Amsterdam
Netherlands
1066 EC

Study participating centre
Spaarne Gasthuis
Haarlem
Netherlands
2035 RC

Study participating centre
St Antonius Ziekenhuis
Nieuwegein
Netherlands
3435 CM

Study participating centre

Albert Schweitzer Ziekenhuis
Dordrecht
Netherlands
3318 AT

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7334 DZ

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9728 RW

Study participating centre

BovenIJ ziekenhuis
Amsterdam
Netherlands
1034 CS

Sponsor information

Organisation
Academisch Medisch Centrum

Sponsor details
Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor type
Other

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Zorgverzekeraars Nederland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request. After the completion of the trial the researchers will analyse the data and publish the relevant details. Two years after the publication of their article they will make the raw data available upon request. The request can be sent to a yet to be determined member of the steering committee. The reason for the request shall be evaluated by the steering committee and if the reason is deemed appropriate the raw data will be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4.2	26/09/2017	26/09/2017	No	Yes
Protocol file	version 5.0	29/01/2018	02/08/2023	No	No
Statistical Analysis Plan	version 1.0	17/07/2023	02/08/2023	No	No
Results article		14/06/2025	16/06/2025	Yes	No