

The Dutch injection versus operation trial in carpal tunnel syndrome patients

Submission date 21/06/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/07/2017	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/06/2025	Condition category Nervous System Diseases	<input type="checkbox"/> 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

Contact information

Type(s)

Scientific

Contact name

Prof Rob de Bie

Contact details

Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

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

Study participating centre
Alrijne Ziekenhuis
Leiderdorp
Netherlands
2353 GA

Study participating centre
Catharina Ziekenhuis
Eindhoven
Netherlands
5623 EJ

Study participating centre
Elkerliek Ziekenhuis
Helmond
Netherlands
5707 HA

Study participating centre
Het LangeLand Ziekenhuis
Zoetermeer
Netherlands
2725 NA

Study participating centre
Maastricht UMC+
Maastricht
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
Netherlands
2625 AD

Study participating centre

Sionsberg

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Netherlands
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

Study participating centre

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Netherlands
7000 AD

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Gelre Ziekenhuis

Apeldoorn
Netherlands
7334 DZ

Study participating centre

Flevoziekenhuis

Almere
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1315 RA

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Gouda
Netherlands
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Study participating centre**Martini Ziekenhuis**

Groningen
Netherlands
9728 RW

Study participating centre**BovenIJ ziekenhuis**

Amsterdam
Netherlands
1034 CS

Sponsor information**Organisation**

Academisch Medisch Centrum

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

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?
Results article		14/06/2025	16/06/2025	Yes	No
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes