

# The Dutch injection versus operation trial in carpal tunnel syndrome patients

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

**Study website**

<https://www.districts.nl/>

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Rob de Bie

**Contact details**

Meibergdreef 9  
Amsterdam  
Netherlands  
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

**Study participating centre**  
**Alrijne Ziekenhuis**  
Leiderdorp  
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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**  
Dokkum  
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9101 DC

**Study participating centre**  
**MC Slotervaart**  
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1066 EC

**Study participating centre**  
**Spaarne Gasthuis**  
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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**  
**Slingeland Ziekenhuis**  
Doetinchem  
Netherlands  
7000 AD

**Study participating centre**  
**Gelre Ziekenhuis**  
Apeldoorn  
Netherlands  
7334 DZ

**Study participating centre**  
**Flevoziekenhuis**  
Almere  
Netherlands  
1315 RA

**Study participating centre**  
**Groene Harts Ziekenhuis**  
Gouda  
Netherlands  
2803 HH

**Study participating centre**  
**Martini Ziekenhuis**  
Groningen  
Netherlands  
9728 RW

**Study participating centre**

**BovenIJ ziekenhuis**  
Amsterdam  
Netherlands  
1034 CS

## Sponsor information

### Organisation

Academisch Medisch Centrum

### Sponsor details

Meibergdreef 9  
Amsterdam  
Netherlands  
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

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