

# Splinting or surgery for carpal tunnel syndrome

<b>Submission date</b> 11/02/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/10/2022	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
OG97-013

## Study information

**Scientific Title**

Splinting or surgery for carpal tunnel syndrome

**Study objectives**

1. To determine the short and long-term efficacy of splinting compared with early surgery in relieving Carpal Tunnel Syndrome (CTS) symptoms
2. To assess from a societal perspective the cost-effectiveness of these treatment options

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Medical Ethics Committees of the 13 participating hospitals approved the study protocol.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Carpal tunnel syndrome

**Interventions**

1. Wrist splint
2. Open carpal tunnel release

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. General improvement, scored by the patient on a 6-point ordinal transition scale, ranging from 'completely recovered' to 'much worse'
2. The number of nights that the patient awoke, due to the symptoms, during the past week
3. The severity of the most important symptoms

In order to study short and long-term treatment effects, data are collected in the hospital at baseline and at 3, 6 and 12 months after randomisation. Additional postal questionnaires are sent to the patients in the months that they do not visit the hospital (1, 2, 4, 5, 7, 8, 9, 10 and 11 months after randomisation), and again 18 months after randomisation.

### **Secondary outcome measures**

1. Patient satisfaction, using an 11-point numerical rating scale, ranging from 0 'very unsatisfied' to 10 'completely satisfied'
2. Use of pain medication for the symptoms during the past week (yes/no)
3. The severity of symptoms and functional status, assessed by means of a self-administered questionnaire, containing two scales (the Symptom Severity Scale and the Functional Status Scale)
4. The overall severity of CTS complaints
5. Results of electrodiagnostic studies

Other outcome measures:

1. Compliance with treatment
2. Adverse effects
3. Direct and indirect costs
4. Success of blinding

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### **Overall study start date**

01/01/2002

### **Completion date**

01/01/2003

## **Eligibility**

### **Key inclusion criteria**

1. Pain, paraesthesias and/or hypoesthesias in the hand, in the area innervated by the median nerve
2. Clinical diagnosis of CTS has to be confirmed by electrodiagnostic studies
3. Aged 18 years or older
4. Able to complete written questionnaires (in Dutch)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

**Target number of participants**

190

**Total final enrolment**

176

**Key exclusion criteria**

1. Already been treated with a wrist splint or have had previous carpal tunnel release
2. A history of wrist or median nerve injury from trauma (e.g. contusion, fractures) or prior surgery on the wrist
3. A history suggesting underlying causes of CTS, such as diabetes mellitus, thyroid disease, rheumatoid arthritis, chronic renal failure treated by hemodialysis, space-occupying lesions in the volar wrist area, anatomic abnormalities of the wrist or hand
4. Pregnancy or lactation
5. Clinical signs or symptoms, or electrodiagnostic studies suggesting conditions that could mimic CTS or interfere with its validation, such as cervical radiculopathy, brachial plexopathy, thoracic outlet syndrome, pronator teres syndrome, ulnar neuropathy, polyneuropathy, Raynaud's disease or sympathetic dystrophy
6. Severe thenar muscle atrophy

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

01/01/2003

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**EMGO-Institute**

Amsterdam

Netherlands

1081 BT

## **Sponsor information**

**Organisation**

Dutch Health Care Insurance Company (The Netherlands)

**Sponsor details**

-  
Amsterdam  
Netherlands  
-

**Sponsor type**  
Government

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Dutch Health Care Insurance Company (The Netherlands) (ref: OG 97-013)

**Funder Name**  
Anna Fonds Foundation (The Netherlands)

## Results and Publications

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		18/12/2001		Yes	No
<a href="#">Results article</a>		11/09/2002	27/10/2022	Yes	No