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# Splinting or surgery for carpal tunnel syndrome

**Submission date**
11/02/2002

**Recruitment status**
No longer recruiting

**Registration date**
11/02/2002

**Overall study status**
Completed

**Last Edited**
27/10/2022

**Condition category**
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**Protocol serial number**
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.

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## 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(s)
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.

## Key secondary outcome(s)
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

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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### 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
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# Sponsor information

**Organisation**
Dutch Health Care Insurance Company (The Netherlands)

# 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

## 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? |
|---|---|---|---|---|---|
| Results article | | 11/09/2002 | 27/10/2022 | Yes | No |
| Protocol article | | 18/12/2001 | | Yes | No |