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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.

Study design
Randomised controlled trial

Primary study design
Interventional

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
Netherlands
1081 BT

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