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Evaluation of wrist splinting for the treatment of carpal tunnel syndrome

Submission date
24/04/2018

Recruitment status
No longer recruiting

Registration date
02/05/2018

Overall study status
Completed

Last Edited
20/12/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Carpal tunnel syndrome (CTS) is pressure on a nerve in the wrist that causes tingling, numbness and pain in the hand and fingers. It is commonly treated with wrist splinting, mainly during night-time, but the evidence for the effectiveness and durability of this treatment is weak. The most common type of splint used in current clinical practice is a rigid splint that immobilizes the wrist. However, it has not been established whether a rigid splint is better than a soft splint that does not immobilize the wrist. The aim of this study is to assess the effectiveness of a rigid wrist splint compared with that of a soft wrist splint in patients with CTS.

Who can participate?
Patients aged 25 to 65 with CTS

What does the study involve?
Participants are randomly allocated to treatment with either a rigid or soft wrist splint to be used at night and if possible during daytime, at first for 6 weeks. The splints are fitted with a temperature monitoring device to measure the total time during which the splint has actually been worn. The participants complete a questionnaire that measures CTS symptoms, health status, quality of life and pain at the start of treatment and after 6, 12, 24 and 52 weeks. The participants undergo physical examinations and nerve conduction testing at the start of the study and at 52 weeks.

What are the possible benefits and risks of participating?
The results from the study are of great importance to patients who will be treated in the future for CTS. They will show the long-term effects of treatment of CTS with a wrist splint. The use of a wrist splint does not have any complications and participation in the study does not cause delayed treatment time compared with routine treatment.

Where is the study run from?
Department of Orthopedics, Hässleholm-Kristianstad-Ystad (Sweden)

When is the study starting and how long is it expected to run for?
January 2018 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Kamelia Tadjerbashi

Contact information

Type(s)
Scientific

Contact name
Dr Kamelia Tadjerbashi

Contact details
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Kristianstad
Sweden
29185

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018/16

Study information

Scientific Title
Treatment of carpal tunnel syndrome with wrist splinting: a randomized controlled trial

Study objectives
Wrist splinting is effective for treatment of carpal tunnel syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/01/2018, Regional Ethical Review Board (Lund, Sweden), ref: 2018/16
2. Amendment approved 16/02/2021, Ethical Review Authority (Sweden), ref: 2021-00656

Study design

Multi-centre prospective assessor-blinded randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Carpal tunnel syndrome

Interventions
Current intervention as of 28/04/2021:
A total of 112 eligible patients who accept participation and provide informed consent will be randomized according to a computer-generated list to treatment with either rigid or soft wrist splint to be used at night and if possible during daytime, initially for 6 weeks.

Group A: Splint with metal bar
A standard splint with wrist in neutral position worn at night and if possible during daytime. If after 6 weeks the patient reports large improvement, no further treatment is given. If the patient reports small or no improvement, further treatment with splint is given for another 4 weeks. If the patient reports only small or no improvement after 10-week splinting the patient will be offered surgery. Patients who refuse further treatment with wrist splinting will be offered surgery. Surgery will not be performed before 12 weeks after treatment start. If symptom recurrence occurs after improvement, the patients will be offered 4 weeks of wrist splinting. If the patient reports small or no improvement the patient will be offered surgery. Patients who refuse further treatment with wrist splinting will be offered surgery.

Group B: Soft splint
The splint is worn at night and if possible during daytime. If at the end of the 6 weeks the patient reports large improvement, no further treatment is given. If the patient reports small or no improvement the patient is offered surgery. Surgery will not be performed before 12 weeks after treatment start. If the patients reports symptom recurrence the patient will receive 4 weeks of similar splint. If the patient reports small or no improvement the patient is offered surgery.

The splints will be fitted with a temperature monitoring device to ascertain the total time during which the splint has actually been worn. The trial participants will complete a questionnaire that includes the 6-item CTS symptoms scale (CTS-6), the 11-item disabilities of the arm, shoulder and hand (QuickDASH) scale, the Euro-Qol 5-dimentions (EQ-5D) health status and quality of life measure and the palmar pain scale at trial start and at 6, 12, 24 and 52 weeks after treatment

start. The participants will undergo physical examination and nerve conduction testing at trial start and at 52 weeks. The trials primary outcome is the change in the CTS-6 score from trial start, to 6 and 12 weeks and the rate of carpal tunnel release surgery at 52 weeks.

From patient 113 and onwards, the randomization process and interventions will be exactly the same as described above, however, the trial participants will complete the questionnaire only at baseline, and at 6 and 12 weeks after treatment start, since the follow-up time for these patients be 12 weeks (time frame for the trial's first primary outcome measure). Patient 113 and onwards will undergo physical examination and nerve conduction testing at trial start but not at 52 weeks. No other changes will be made in the trial protocol for these patients.

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Group B: Soft splint
The splint is worn at night and if possible during daytime. If at the end of the 6 weeks the patient reports large improvement, no further treatment is given. If the patient reports small or no improvement the patient is offered surgery. Surgery will not be performed before 12 weeks after treatment start. If the patients reports symptom recurrence the patient will receive 4 weeks of similar splint. If the patient reports small or no improvement the patient is offered surgery.

The splints will be fitted with a temperature monitoring device to ascertain the total time during which the splint has actually been worn. The trial participants will complete a questionnaire that includes the 6-item CTS symptoms scale (CTS-6), the 11-item disabilities of the arm, shoulder and hand (QuickDASH) scale, the Euro-Qol 5-dimentions (EQ-5D) health status and quality of life measure and the palmar pain scale at trial start and at 6, 12, 24 and 52 weeks after treatment start. The participants will undergo physical examination and nerve conduction testing at trial start and at 52 weeks. The trials primary outcome is the change in the CTS-6 score from trial start, to 6 and 12 weeks and the rate of carpal tunnel release surgery at 52 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome measure
1. Change in CTS symptoms, measured with the 6-item CTS symptoms scale at baseline, 6 weeks and 12 weeks
2. Rate of surgery at 52 weeks, measured in percent (proportion of patients that had surgery within 52 weeks)

Secondary outcome measures
1. TS symptoms, measured with the 6-item CTS symptoms scale score at 52 weeks
2. Activity limitations, measured with the 11-item disabilities of the arm, shoulder and hand (QuickDASH) scale score at baseline, 12 weeks and 52 weeks
3. Health status and quality of life, measured with the EQ-5D index at baseline, 12 weeks and 52 weeks
4. Grip strength, measured with the Jamar dynamometer at baseline and 52 weeks
5. Patient satisfaction, measured with the visual analogue scale (VAS) at 12 weeks and 52 weeks
6. Palmar pain, measured with the 2-item palmar pain scale at 52 weeks
7. Time to surgery, measured in weeks, within 52 weeks
8. Duration of sick leave, measured in days/weeks/months during 52 weeks
9. Adverse events

Overall study start date
02/01/2018

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/06/2018:
1. Primary, idiopathic carpal tunnel syndrome (CTS)
2. Age 25-65 years, either sex
3. Symptoms of classic or probable CTS according to the criteria in Katz hand diagram
4. Nerve conduction studies showing median neuropathy at the wrist and no other abnormalities or, in the presence of normal nerve conduction study results, two orthopedic or hand surgeons independently diagnose the patient as having CTS
5. Symptom duration of at least 1 month

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2. Age 25-65 years, either sex
3. Symptoms of classic or probable CTS according to the criteria in Katz hand diagram
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5. Symptom duration of at least 1 month
6. Symptom severity score at least 1.8 on the 6-item CTS symptoms scale (CTS-6)

Participant type(s)

Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
112

Total final enrolment
142

Key exclusion criteria
1. CTS classified as severe (thenar atrophy or 2-point discrimination exceeding 8 mm in at least 1 finger)
2. Treatment of the study hand with a wrist splint in the past year
3. Previous steroid injection for CTS in the study hand
4. Inflammatory joint disease
5. Vibration-induced neuropathy
6. Polyneuropathy
7. Current pregnancy
8. Trauma to the study hand in the past year
9. Previous CTS surgery in the study hand
10. Inability to complete questionnaires due to language difficulties or cognitive disorder
11. Severe medical illness
12. Known abuse of drugs and/or alcohol

Date of first enrolment
04/06/2018

Date of final enrolment
21/12/2021

Locations

Countries of recruitment
Sweden

Study participating centre

Department of Orthopedics, Hässleholm-Kristianstad-Ystad
Sweden
29185

Sponsor information

Organisation
Region Skåne

Sponsor details
VO Ortopedi, Skånevård Kryh
Hässleholm
Sweden
28125

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03sawy356

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The trialists intend to publish the study protocol with statistical analysis plan in an appropriate journal during 2018. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 05/01/2022:
The datasets generated and analysed during the current study are not expected to be made

available as the study team do not have ethical approval or participant consent for making individual patient data publicly available.

Previous individual participant data (IPD) sharing statement:
The trialists are not allowed to share individual patient data but can consider reasonable requests from researchers. The data will be stored at the trial researchers' institution.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/08/2019	29/08/2019	Yes	No