

Prospective clinical trial comparing C-Trac™ splint with conventional resting splint for treatment of carpal tunnel syndrome

Submission date 18/05/2006	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 22/06/2006	Overall study status Completed	☐ Protocol
Last Edited 31/07/2014	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

RD/33646/1, 06/Q2401/77

Study information

Scientific Title

Acronym

C-Trac

Study objectives

C-Trac™ is a safe and useful splint for treating carpal tunnel syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Derbyshire Research Ethics Committee, 18/08/2006, ref: 06/Q2401/77; Trust ref: DHRD/2006/037

Primary study design

Interventional

Study design

Prospective randomised controlled clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Carpal tunnel syndrome

Interventions

Comparing the C-Trac™ splint versus the conventional resting splint

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Levine questionnaire scores in each group at 8 weeks

Key secondary outcome(s)

1. Grip, pinch and sensation scores at 8 weeks
2. Levine questionnaire scores, grip, pinch and sensation scores at 0 and 4 weeks and at 6, 12, 24 and 60 months

Completion date

21/06/2011

Eligibility**Key inclusion criteria**

Patients less than 65 years of age presenting to the Pulvertaft Hand Centre with a diagnosis of mild or moderate carpal tunnel syndrome, confirmed by nerve conduction studies and clinical assessment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe carpal tunnel syndrome (based on nerve conduction studies and clinical assessment)
2. Previous carpal tunnel decompression on affected wrist
3. Previous steroid injection into affected carpal tunnel
4. 65 years of age or older
5. History of gout, hypothyroidism, previous fragility fracture, symptomatic basal joint arthritis, septic or rheumatoid arthritis of the hand, previous wrist fracture, diabetes mellitus, pregnancy, amyloidosis, acromegaly, renal dialysis, current oral steroid use
6. Current or very recent involvement in hand or related research
7. Regular use of hand-held vibrating tools
8. Ongoing involvement in compensation cases
9. Contact allergy to rubber or plastics
10. Patients who are unable to give informed consent

Date of first enrolment

22/06/2006

Date of final enrolment

21/06/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Pulvertaft Hand Centre

Derby

United Kingdom

DE1 2QY

Sponsor information

Organisation

Derby Hospitals NHS Foundation Trust (UK)

Funder(s)

Funder type

Industry

Funder Name

Heritage Medical Ltd. will initially contribute 25 C-Trac™ splints to the study, at a retail cost of £5000, and should C-Trac™ prove to be effective, further C-Trac™ splints will be provided.

Results and Publications

Individual participant data (IPD) sharing plan

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		06/06/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes