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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/06/2006	**Overall study status** Completed	
Last Edited 31/07/2014	**Condition category** Nervous System Diseases	

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
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

Study design
Prospective randomised controlled clinical trial

Primary study design
Interventional

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes