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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

**Registration date**
22/06/2006

**Overall study status**
Completed

**Last Edited**
31/07/2014

**Condition category**
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.pulvertafthandcentre.org.uk

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Frank Burke

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

**Secondary study design**
Randomised controlled trial

**Study setting(s)**
Other

**Study type(s)**
Treatment

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

**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 measure
Levine questionnaire scores in each group at 8 weeks

### Secondary outcome measures
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

### Overall study start date
22/06/2006

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
25 patients in each group

### 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**
England

United Kingdom

**Study participating centre**
**Pulvertaft Hand Centre**
Derby
United Kingdom
DE1 2QY

# Sponsor information

**Organisation**
Derby Hospitals NHS Foundation Trust (UK)

**Sponsor details**
Assistant Director of Research and Development
Research and Development Office
Derby Hospitals National Health Service (NHS) Foundation Trust
University of Nottingham Medical School at Derby
Derby City General Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3DT

**Sponsor type**
Hospital/treatment centre

# 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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |