

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

<b>Submission date</b> 18/05/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/07/2014	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Frank Burke

**Contact details**  
Pulvertaft Hand Centre  
Derby Royal Infirmary  
London Road  
Derby  
United Kingdom  
DE1 2QY

## 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?
<a href="#">Results article</a>		06/06/2013		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes