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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
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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
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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