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A prospective, comparative analysis of commercial and customised thumb splints in osteoarthritis effects on pain, hand function and patient preference.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 25/04/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0185146346

Study information

Scientific Title

Study objectives
Osteoarthritis of the thumb and splinting:
1. To contrast and compare levels of pain relief and scores on hand functions between the splints
2. To contrast and compare patients views of each splint in terms of pain relief, hand function and cosmesis
3. To compare this to the theoretical basis of splinting, and findings of previous studies in this area
4. To make recommendations for how practice can be improved
5. The null hypothesis is: there is no significant difference between customised and commercial splints with reference to pain levels, hand function and patient preference.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective, longitudinal study with a randomised cross over design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Osteoarthritis (OA)

Interventions
At the first appointment a Baseline assessment will be carried out , and the patient will be randomly allocated either a hard/ customised or soft/commercial splint, to be worn for two weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain will be measured using a visual analogue scale, hand function will be assessed using the arthritis hand function test, and patient preference by using a questionnaire.

After randomisation, the patients will be reassessed, using the same assessments, with the said splint in situ. At this point they will be given a questionnaire to fill out, at home, within a week. At the third appointment they will be given the second, different type of splint to wear for two weeks. The same procedure of appointments and assessments as for the first splint will be repeated. At the final appointment patients will be asked which splint, if any, they prefer, and they will take this one away with them. Results gained will then be compared and contrasted as set out in the research proposal.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/09/2002

Completion date
20/04/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
10/09/2002

Date of final enrolment
20/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Occupational Therapy Department
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name

Plymouth Hospitals NHS Trust (UK), Own Account

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