

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/04/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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Sponsor information**Organisation**

Department of Health

Sponsor details

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Sponsor type

Government

Website

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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