

# A randomised trial to compare the impact of the McKenna thumb shield and Colditz splints upon functional ability and pain levels of patients with osteoarthritis of the first carpometacarpal joint

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/04/2015	<b>Condition category</b> Musculoskeletal Diseases	<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

### Contact name

Mr J Holmes

### Contact details

Derby Hospitals NHS Foundation Trust  
Pulvertaft Hand Centre  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0077170554

## **Study information**

### **Scientific Title**

A randomised trial to compare the impact of the McKenna thumb shield and Colditz splints upon functional ability and pain levels of patients with osteoarthritis of the first carpometacarpal joint

### **Study objectives**

1. Establish the short and longer term (12 months) effect of the Colditz and McKenna Thumb Shield splints on pain and function for patients with symptomatic OA at base of thumb.
2. Compare the results of above to determine whether the Colditz or McKenna Thumb Shield is more effective at reducing pain and increasing function.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Musculoskeletal Diseases: Osteoarthritis

### **Interventions**

Patients, referred by the GP, who attend the Pulvertaft Hand Centre at the Derbyshire Royal Infirmary (DRI), presenting with pain and/or instability at the basal thumb joint resulting from osteoarthritis.

The patients will be screened and have an x-ray, as normal, in the Pulvertaft Hand Clinic by a Consultant or Specialist Registrar. The Doctor will then grade the stage of the osteoarthritis by

using the Eaton Littler scale. If appropriate they will then be referred onto the occupational therapist or physiotherapist for further assessment and treatment as normal.

The Occupational Therapist in the clinic will receive the referral and then pass it onto the research Occupational Therapist. The research therapist will explain to the patient what is involved in the study and will give them a patient information sheet to take home and read. The research therapist will arrange to phone the patient within 2-3 days to check if they have any queries about the study and to see if they would like to participate. If the patient does not wish to participate, treatment will be organised as normal. For those patients happy to take part in the study, an appointment will be made to obtain written consent and carry out the initial assessment. It will be made clear to the patient that they may withdraw from the study at any time.

Prior to the appointment, the medical notes and x-rays will be obtained to assist in the assessment process. If the patient meets the inclusion criteria the therapist will then go over the patient information about the study again and if the patient is still willing to participate then a consent form will be completed. If consent to participate is not obtained the patient will be treated as normal by the Research Occupational Therapist and then follow up will be arranged with the Hand Therapy workshop team.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

The difference or equivalence of the pain decrease and function increase between the two splinting methods, by comparison of results from the initial assessment, 3 month and 12 month assessments.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/01/2006

### **Completion date**

31/03/2007

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of osteoarthritis of the first carpometacarpal joint
2. Pain at base of thumb
3. Those who are able to give informed voluntary consent

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Dislocated basal thumb joint
2. Multiple joint involvement of the hand
3. Neurological disease
4. Rheumatoid arthritis
5. Previous McKenna thumb shield or Colditz splint supplied
6. Those who are unable to give informed voluntary consent

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

31/03/2007

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Derby Hospitals NHS Foundation Trust**

Derby

United Kingdom

DE1 2QY

## Sponsor information

**Organisation**

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**Sponsor type**  
Government

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

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

## **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