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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

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
29/04/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration