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A prospective randomised study of carpometacarpal joint replacement and trapezectomy in the treatment of trapeziometacarpal osteoarthritis

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Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 15/12/2015	**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

N0077092723

Study information

Scientific Title
A prospective randomised study of carpometacarpal joint replacement and trapezectomy in the treatment of trapeziometacarpal osteoarthritis

Study objectives
The study aims to identify and quantify differences in outcome between two forms of surgical treatment for carpometacarpal osteoarthritis in order to determine if one is superior.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Trapeziometacarpal osteoarthritis

Interventions
This study is designed as a prospective randomised comparison of carpometacarpal joint replacement with trapezectomy.

Consent Procedure:
This will be conducted in accordance with the guidelines issued by the Southern Derbyshire Local Research Ethics Committee. Patients fulfilling the entry criteria will be introduced to the study by one of the principal investigators as part of their normal outpatient clinical assessments. This will provide the opportunity to obtain and inspect recent x-rays before detailed discussion of the study has taken place. Patients wishing to consider participation in the

study will be provided with the patients' information document and arrangements made for further discussion on a separate occasion.

Randomisation:
Patients will be allocated to one of the two treatment groups (trapezectomy carpometacarpal joint replacement) on a randomised basis. At the time of consent each patient entering the study will be allocated, in sequence, a study number. A list of randomly generated numbers, obtained from the Derby University consultancy for Health Science Statistics, will be used to determine which treatment group each patient is allocated to. Each patient will retain both his study number and treatment allocation number from the point of consent throughout the study irrespective of subsequent withdrawal.

Assessment Methodology:
The prospective study design requires that comparable assessments are made before treatment and on a number of occasions thereafter. Assessments will fall into three groups:
1. Assessment of symptoms and disability
2. Quantitative assessment of function
3. Radiographic assessment

Assessment of symptoms and disability:
Symptoms and disability will be assessed using a questionnaire method. The Hand Unit already has some experience using the DASH (Disability Arm Shoulder Hand) questionnaire specifically designed to score upper limb function, and this will be employed in this study. (Hudak et al 1996). This will be supplemented by a detailed assessment of pain and related disability using the Schultz upper extremity pain assessment questionnaire. This includes both visual analogue and categorical questions to characterise pain and its effects. Employment status will be recorded at each assessment.

Quantitative assessment of function:
This will be carried out in accordance with the following protocol drawn-up by the Occupational Therapy Department at The Pulvertaft Hand Centre for the purposes of this study.
Active range of movement Baltimore Therapeutic Equipment (BTE) strength assessment including the following in both static and dynamic modes: Power grip, Three point pinch, Key pinch, Screwdriver grip - pronation Screwdriver grip - supination. Static measurements will be expressed as force in Newtons. Dynamic measurements will enable a calculation to be made of work capacity in Joules to take into account the variation in force and endurance between assessments.

Radiographic assessment:
Pre-operative x-rays will be classified according to radiographic severity. The Eaton Littler classification system will be used (Eaton et al 1985). Post-operative x-rays will be assessed for evidence of component loosening.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Questionnaire-based assessment of disability
2. Quantitative assessment of function using BTE machine
3. Radiographic assessment with plain X-rays

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/09/2001

Completion date
01/09/2003

Eligibility

Key inclusion criteria
Patients referred to the Pulvertaft Hand Centre for treatment of symptomatic carpometacarpal osteoarthritis.
1. Patients entering the study will be drawn from those people presenting to The Pulvertaft Hand Centre for treatment of symptomatic osteoarthritis affecting the trapeziometacarpal joint of one or both thumbs. It is proposed that those centres in the Trent Region that currently refer patients to The Pulvertaft Hand Unit should be informed of this study and that some of their patients may be considered suitable to participate.
2. Patients should be willing to participate in the study after consulting the patient information document and having had the opportunity to discuss the nature of the study with one of the investigators. They will have signed their consent to this effect.
3. Patients entering the study will have exhausted non-operative forms of treatment.
4. Patients must be suitable to undergo both procedures.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Unsuitable to undergo both procedures. Preoperative x-rays show that degenerative change is not confined to the trapeziometacarpal joint but is more widespread, especially where the scaphotrapezial and scaphotrapezoid joints are involved. Patients, while suitable for trapezectomy, would not be considered suitable for carpometacarpal joint replacement. The extent of degenerative change will be defined as follows.
1.1 Any intercarpal joint, particularly the scaphotrapezial and scaphotrapezoid joints where the radiographic joint space is reduced to less than 50% of normal.
1.2 Any clinical or radiographic evidence of radiocarpal joint degeneration.
1.3 Rare occasions when the extent of bony collapse affecting the trapezium and signifying osteonecrosis may be such as to preclude carpometacarpal joint replacement.
2. 55 years of age or younger
3. Current or previous history of septic arthritis involving the affected wrist.
4. Suffering from rheumatoid arthritis or other inflammatory arthritides.

5. Patients not willing to participate.
6. Suffering from mental illness precluding their participation in the consent process.

Date of first enrolment
01/09/2001

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derbyshire Royal Infirmary
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (UK)

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