

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

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|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
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| <b>Registration date</b><br>12/09/2003 | <b>Overall study status</b><br>Stopped                | <input type="checkbox"/> Protocol                    |
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|                                        |                                                       | <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

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

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

Treatment

### **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(s)**

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

## **Key secondary outcome(s)**

Not provided at time of registration

## **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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Derbyshire Royal Infirmary**  
Derby  
United Kingdom  
DE1 2QY

## **Sponsor information**

**Organisation**  
Department of Health (UK)

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Southern Derbyshire Acute Hospitals NHS Trust (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration