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Excision of the trapezium for osteoarthritis of the trapeziometacarpal joint. Is there any benefit to ligament reconstruction?

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 17/04/2008	**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
N0123138157

Study information

Scientific Title

Study objectives
To see if the longer recovery time for the more complex operation is justified and produces a better thumb than the simpler operation.

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
Trapeziometacarpal osteoarthritis

Interventions
Patients randomised to:
1. Simple trapeziectomy
2. Trapeziectomy with palmaris longus interposition
3. Trapeziectomy with ligament reconstruction and tendon interposition using 50% of the flexor carpi radialis tendon

All patients wore a thumb splint for 6 weeks. Patients were followed up for 1 year.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

Completion date
01/09/2006

Eligibility

Key inclusion criteria
Patients with osteoarthritis of the trapeziometacarpal join.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
183

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2001

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester

United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	One-year results	01/11/2004		Yes	No