Randomised controlled trial comparing dermofasciectomy and full thickness skin grafting vs fasciectomy and Z-plasties for the surgical treatment of Dupuytren's contracture of the hand.

Submission date	Recruitment status	Prospectively registered		
30/09/2004	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited 17/12/2009	Condition category Musculoskeletal Diseases	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Aamer Ullah

Contact details

University Hospitals of Leicester c/o Research and Development Office Leicester General Hospital NHS Trust Leicester United Kingdom LE1 4PW +44 (0)116 258 4109 nicola.turner@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0123137985

Study information

Scientific Title

Study objectives

To see if skin grafting will reduce the incidence of recurrence in the surgical treatment of Dupuytren's contracture when compared to fasciectomy and skin closure.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Dupuytren's disease

Interventions

Determine recurrence rates in operated Dupuytren Patients undergoing fasciectomy or full thickness skin grafts

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Recurrence rate and severity
- 2. Differences in patient satisfaction

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2000

Completion date

01/09/2003

Eligibility

Key inclusion criteria

Selected from outpatients clinics in Orthopaedic unit

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Added 17/12/09: 79 patients

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2000

Date of final enrolment

01/09/2003

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

Not defined

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	results	01/03/2009		Yes	No