

Comparison of fasciotomy with fasciectomy in the treatment of Dupuytren's contracture

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/10/2013	Condition category Musculoskeletal Diseases	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0237086821

Study information

Scientific Title

Study objectives

To compare the long term outcomes of treatment of palmar bands with metacarpophalangeal joint (MCPJ) contracture by fasciotomy with fasciectomy.

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

Patients will be randomised to undergo either fasciotomy or fasciectomy. Both procedures will be performed under general anaesthetic with an upper arm tourniquet as a day case, unless contraindicated, in which case admission will be arranged. Both procedures will be performed through 'zig-zag' palmar incisions ensuring identification and protection of the digital nerves.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

There are currently no prospective studies comparing fasciotomy with fasciectomy for patients requiring surgery for palmar Dupuytren's with MCPJ contracture. Currently both procedures are

performed in our unit according to the surgeons preference. Previous retrospective studies have shown benefits of fasciotomy for MCPJ contracture.

Study endpoints: 5 year follow-up observing any disease recurrence and the degree of improvement of MCPJ contracture.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2001

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Recruitment will be from new referrals from out patient clinics. Patients will be included if they are >35 years with palmar Dupuytren's causing contracture at the metacarpophalangeal joint (MCPJ) which interferes with hand function.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Consultant
Prescot, Merseyside
United Kingdom
L35 5DR

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
St Helens and Knowsley 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