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Splinting after Contracture Release for Dupuytren's

Submission date	Recruitment status	[X] Prospectively registered
14/02/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/03/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/01/2018	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
AP1076

Study information

Scientific Title
Splinting after Contracture Release for Dupuytren's: a pragmatic, multi-centre, randomised controlled trial

Acronym
SCoRD

Study objectives
To assess whether the use of post-operative static night splinting provides a better outcome, specifically patient-reported hand function and finger mobility, in patients undergoing fasciectomy or dermofasciectomy for Dupuytrens contracture.

Please note that as of 30/04/2008 the anticipated start and end dates of this trial were updated. The previous dates were:
Previous anticipated start date: 01/07/2007
Previous anticipated end date: 30/01/2009

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Cambridgeshire 2 Research Ethics Committee gave approval on the 26th July 2007 (ref: 07/Q0108/120)

Study design
Pragmatic, multi-centre, 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
Dupuytren's contracture

Interventions

All patients will undergo surgery for contracture release and receive usual post-operative hand therapy. Patients will be randomised at their first post-operative hand therapy appointment to one of two groups: one group will receive a static night splint to be worn for 6 months and the other will not receive a splint.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Self-reported function and disability using the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire.

Endpoint assessment is at 12 months after surgery with interim measures taken at 3 and 6 months.

Secondary outcome measures
1. Range of movement using a hand-held goniometer
2. Patient satisfaction using an 10 point verbal rating scale
3. Recurrence of a contracture in the previously operated field

Endpoint assessment is at 12 months after surgery with interim measures taken at 3 and 6 months.

Overall study start date
01/10/2007

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Aged over 18 years, either sex
2. Awaiting surgical release of Dupuytrens contractures by fasciectomy or dermofasciectomy
3. Have given written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
128

Key exclusion criteria
1. Aged under 18 years
2. Unable to give fully informed consent

Date of first enrolment
01/10/2007

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Allied Health Professions
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

Sponsor details
University Plain
Norwich
England
United Kingdom
NR4 7TJ

Sponsor type
University/education

Website
http://www.uea.ac.uk/

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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?
Protocol article	protocol found at	30/04/2008		Yes	No
Results article	results	21/06/2011		Yes	No