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A feasibility study of treatments for Dupuytren's contracture (HAND-1)

Submission date
19/08/2015

Recruitment status
No longer recruiting

Registration date
28/08/2015

Overall study status
Completed

Last Edited
06/02/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dupuytren’s contracture is a condition that affects the hands and fingers, causing one or more fingers to gradually and irreversibly curl into the palm of the hand. Over time, this prevents the sufferer from being able to use the hand properly, making day to day tasks, such as grooming and shaking hands more difficult. It occurs when the connective tissue in the palm thickens, causing small hard lumps, called nodules, to develop under the skin of the palm. Over time, the nodules can develop to form cords of tissue that then shorten (contract) and pull a finger or thumb towards the palm. There are no agreed guidelines for the surgical treatment of this condition. However, 16,000 surgical procedures were performed in 2011-2012 costing the NHS £50 million. The most common operation is a “limited fasciectomy” (LF), which involves opening up the hand and removing the thickened cords causing the condition. It can be performed under general or regional anaesthesia and has a 4-6 week recovery period. A common alternative treatment is “needle fasciotomy” (NF), which involves inserting a fine needle into the thickened cords to divide them under the skin and release the tightness in the hand. This is performed under local anaesthesia in a clinic room and has a 1-2 week recovery period. The Dupuytren's contracture comes back more commonly after needle fasciotomy than after limited fasciectomy. Little information is available about patient reported outcomes to assess the recovery after Dupuytren’s treatment. A study to compare the outcomes and costs of these two treatments is therefore needed. This is a smaller feasibility study to help with planning of the main study.

Who can participate?
Adults (aged at least 18) with Dupuytren’s contracture.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 have a needle fasciotomy. Those in group 2 have a limited fasciotomy. All participants are then seen on two occasions following their treatment and are also be asked to complete questionnaires at home. Participants may be asked to take part in qualitative interviews for us to understand reasons for trial participation and explore patients’ experiences of the trial and acceptability of the treatments. Members of staff who are recruiting patients to the study may also be interviewed to identify possible recruitment difficulties. The trial takes place over 22 months.

What are the possible benefits and risks of participating?
Taking part in this study may not help the participants directly, but it should help improve future care for patients with Dupuytren's contracture. Both the treatments are available as routine NHS care, so there is no extra risk involved in receiving them as part of the study. For participants taking part in if in the optional interviews, it is possible that talking about their feelings and other issues related to their diagnosis and treatment may cause anxiety, but they are able to pause or finish the discussion with the researcher at any time.

Where is the study run from?
Three NHS Secondary care hospitals in England (UK)

When is the study starting and how long is it expected to run for?
October 2015 to September 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Eleanor Harrison

Study website
www.nottingham.ac.uk/hand1

Contact information

Type(s)
Scientific

Contact name
Mrs Eleanor Harrison

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Contact details
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Derby Road
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NG7 2UH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19243

Study information

Scientific Title
Needle fasciotomy versus limited fasciectomy for the treatment of Dupuytren’s contractures of the fingers: a feasibility study which investigates the acceptability and design of a multicentre randomised controlled trial (RCT)

Acronym
HAND-1

Study objectives
The aim of this study is to evaluate the feasibility of conducting a randomised controlled trial comparing two surgical treatments (needle fasciotomy and limited fasciectomy) for Dupuytren's contracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/EM/0197

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
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
1. Needle fasciotomy - This procedure takes place in an outpatient clinic room setting. The contracture is divided with a needle which pierces the skin (no skin incision)

2. Limited fasciectomy - This procedure takes place in an operating theatre under regional or general anaesthesia. The contracture is surgically removed via an incision

Intervention Type
Other

Primary outcome measure
Multi outcomes; Timepoint(s): baseline, Day of surgery, 2 weeks post-surgery, 6 weeks post-surgery and 6 months post-surgery

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2015

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aged over 18 years.
2. One or more fingers with a Dupuytren’s contracture of >30° in the metacarpophalangeal (MCP) and/or proximal
interphalangeal joints (PIP).
3. Well defined cord(s) causing contracture.
4. No previous surgery for Dupuytren’s contracture on the same hand.
5. Willing to undergo either study procedure.
6. Able to complete follow up assessments.; Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
71

Key exclusion criteria
1. Dupuytren's contracture of the distal interphalangeal joints (DIP) only
2. Planned dermofasciectomy or very limited fasciectomy (excision of =1cm cord segment)
3. Previously recruited into this study for treatment of either hand
4. Life expectancy less than 3 years

Date of first enrolment
03/11/2015

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Queens Medical Centre
Derby Road
Nottingham, Nottinghamshire
United Kingdom
NG7 2UH

Study participating centre
Royal Derby Hospital
Uttoxeter Rd
Derby
United Kingdom
DE22 3NE

Study participating centre
Wrightington Hospital
Hall Ln
Appley Bridge
Wigan
United Kingdom
WN6 9EP

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research; Grant Codes: PB-PG-0613-31083

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	25/08/2017		Yes	No
Results article	results	30/01/2020	06/02/2020	Yes	No
HRA research summary			28/06/2023	No	No