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Study of treatments for Dupuytren's contractures

Submission date
01/09/2020

Recruitment status
No longer recruiting

Registration date
18/09/2020

Overall study status
Ongoing

Last Edited
20/06/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dupuytren's contractures (DC) are scar-like tissue that form under the skin of the palm of the hand, causing one or more fingers to bend into the palm (https://www.nhs.uk/conditions/dupuytrens-contracture/). They prevent them from straightening fully which causes difficulty with many everyday tasks like washing, dressing, or using a computer keyboard. It is common: in 2016 NHS England spent £36 million treating 16,700 patients with DC. DC are most commonly treated using one of two procedures and it is not known which is best. Needle fasciotomy (NF) involves cutting the contracture by moving a medical needle back and forth through it until it snaps, releasing the finger. It can be done in a clinic room and leaves no skin wound. Recovery takes 1-2 weeks 2. Limited fasciectomy (LF) involves cutting out the contractures and stitching the skin up. This is done in an operating theatre with the patient asleep or the arm "frozen". Recovery takes 4-12 weeks. About 8 in 10 treatments done currently are LF. The problem can come back (recur) after either treatment. Studies suggest that this happens sooner and more commonly with NF, but LF has a greater risk of causing other problems which restrict hand function, like finger stiffness and pain. NF is cheaper for the NHS, but any savings may be offset by an increased need for future treatments after recurrence. The aims of this study are to determine whether NF is not substantially worse than LF at preserving hand function and to find out which treatment offers the best value for money.

Who can participate?
Patients aged 18 or over with DC n one or more untreated fingers.

What does the study involve?
Participants will be randomly allocated by a computer to have treatment with either needle fasciotomy or limited fasciectomy. Participants will be followed up after 2, 3, 4 and 6 weeks, and 6, 12 and 24 months. The participant will be asked to complete questionnaires either by post or online for completion at 2, 3 and 4 weeks after the treatment asking about their ability to carry out normal daily activities with the hand, hand function and quality of life. The participant will be asked to complete these again 6 weeks after the treatment (a routine NHS clinic appointment) and at 6, 12 and 24 months at home by post or online. Participants will be asked to take measurements of their finger using a SLiCK device at 6, 12 and 24 months. Participants will be shown how to do this and given an instruction manual at their initial clinic appointments.

Participants will also have access to an online video demonstration of how to do this. The researchers will also compare other measures of hand function, overall health, finger straightness, recurrence and costs. Some people will be contacted up to 2 years after they have had treatment to hear their thoughts on the treatment and about taking part in the study. The discussion will cover hand function before and after treatment, expectations and experiences of the treatment and recovery, and views on taking part in the study. The researchers have arranged to share their results with a research team comparing limited fasciectomy with a third treatment option, collagenase injections, in another study funded by NIHR. This will provide even more information on how best to treat DC.

What are the possible benefits and risks of participating?
There is no direct benefit of taking part in the study, but this study may help us to treat people with Dupuytren's contracture in the future. Participants will receive the same level of care whether they choose to participate in the study or not. Participants may not benefit personally from taking part in this study, but because of the contact with the research team, they will have more regular or frequent opportunity. Both treatments are a part of standard NHS care, so there is no extra risk involved in receiving them as part of the study. Taking part will mean spending some extra time to complete questionnaires but these can be completed online or by post. There are no physical risks if participants take part in the optional interviews. It is possible that participants talking about their feelings and other issues related to their diagnosis and treatment may feel overwhelmed. Participants are able to pause or finish the discussion with the researcher at any time.

Where is the study run from?
Nottingham University Hospitals NHS Trust and Nottingham Clinical Trials Unit (NCTU) (UK)

When is the study starting and how long is it expected to run for?
January 2020 to March 2026

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282087

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 45939, IRAS 282087

Study information

Scientific Title
Hand-2: Needle fasciotomy versus limited fasciectomy for the treatment of Dupuytren’s contractures of the fingers: a randomised, multi-centre non-inferiority trial

Acronym
Hand-2

Study objectives

To establish the clinical and cost-effectiveness of needle fasciotomy (NF) versus limited fasciectomy (LF) for treatment of DC in the NHS in terms of patient-reported hand function and symptoms and resource utilisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/09/2020, London - Chelsea Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2561; chelsea.rec@hra.nhs.uk), REC ref: 20/LO/0911

Study design
Randomized; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dupuytren’s contractures

Interventions
There are two different treatments for Dupuytren's contracture that are most commonly used in the NHS. However, there is no strong evidence about which of these treatments is best for patients or the NHS. The trial design for Hand-2 was guided by a randomised feasibility study (Hand-1 ISRCTN11164292) which demonstrated that Hand-2 can be successfully performed. It showed it is possible to recruit and retain participants to a trial of two very different treatment (needle fasciotomy (NF) and limited fasciectomy (LF)) for DC and allowed selection of appropriate outcome measures which patients consider relevant to this experience It also demonstrated through qualitative interviews the acceptability of this trial to patients and health professionals.

Hand-2 is a multi-centre, two-arm, parallel, randomised, non-inferiority trial comparing the outcome of NF and LF among adults eligible for treatment of DC within the NHS. An internal pilot phase with an integrated QuinteT Recruitment Intervention (QRI) will be used to optimise the trial design. Potential participants will be identified by the local research team at sites from the GP referral letters and clinic lists. A short version of the information leaflet will be sent to potentially eligible patients explaining Dupuytren’s contractures and the study before their clinic appointment.

This will enable us to assess how the study is explained to patients and how they are invited to take part. If they give permission, they will be asked to complete an audio-recording consent form. If they do not wish to be further approached for the study, they will have the option of opting out by letting any member of clinic staff know.

If after being told about the study by the surgeon and researcher, and reading a full patient information sheet, the patient wishes to take part, they will be asked to sign a consent form.

This may take place on the same day as the clinic appointment, or the patient can consent on another day agreed with the researcher. They will be asked to complete a questionnaire and a researcher will take some measurements of the hand. Their surgical treatment will then be determined at random, and the patient will be informed verbally and in writing which of the following two treatments they will receive:
1. Needle fasciotomy – performed in a clinic room under local anaesthetic
2. Limited fasciectomy – performed in an operating theatre under regional or general anaesthetic.

Patients in the study will join the usual NHS waiting list for their treatment. Other than receiving their allocated treatment and completing one questionnaire about their current hand functionality, there are no other study procedures for patients to complete on the day of surgery. At 2, 3, and 4 weeks after treatment participants will be asked to complete questionnaires regarding their recovery from treatment. Six weeks after treatment participants will be asked to attend a clinic appointment that is part of their usual NHS care. At this appointment, we will ask participants to complete questionnaires and have further measurements taken of their hand. At 3, 6, 12 and 24 months after treatment participants will be asked to complete further questionnaires about their recovery, hand function and quality of life. We will use reminders to ensure data collection.

Reminders may be used. For the earlier timepoints, this may be a text message or e-mail on the day that the questionnaire is due. For the later time points (e.g. 12 and 24 months) this reminder will be sent approximately 2 weeks and 4 weeks after the questionnaire is due. The 24-month follow-up will capture early DC recurrences, which may be extended to 5 years and participants will be asked to consent to this.

Participant questionnaires contain standard questions that are used to assess how the hand looks, feels and works before and after treatment.

In addition at 6 weeks, 6, 12 and 24 months data will be collected about NHS resource use (visits to other health care professionals such as GPs, and any other treatments that participants may have used). Measurement of the angle of straightness of the affected finger(s) and grip strength will be taken at the clinic visit at 6 weeks. In addition, linear measurements of extension and flexion of the study finger will be obtained by the participant at home using the SLiCK device.

Evidence of patient experience and acceptability of treatment for DC in the long term is limited. Hand-2 participants will be invited to take part in qualitative interviews (by phone or face to face) to explore their experiences and the acceptability of treatment. Up to 30 semi-structured interviews will be conducted and some participants may be interviewed more than once to assess if views change over time.

Patients can agree to take part in none, all or some of the three components of this study, and consent will be taken for each component:
1. Audio recording of consultation(s) with the surgeon or other clinic staff
2. The feasibility trial, where surgical treatment is decided randomly
3. Qualitative interviews

Members of staff who are recruiting patients to the study may also be interviewed to assess their views on the trial and its conduct, including knowledge of the evidence and personal views about the interventions, how they explain the study to patients and perceived barriers to recruitment. This can help to highlight possible recruitment difficulties.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Participant-reported assessment of hand function using the PEM questionnaire at 12 months post-treatment intervention

Key secondary outcome(s))
1. Participant-reported hand function and hand health measured using the Hand Health Profile of the PEM at 3 weeks, 6 weeks, 3 months, 6 months and 24 months post-treatment intervention
2. Participant-reported assessment of location-specific health (the hand) using the Single Assessment Numeric Evaluation (SANE) tool and the Measure Yourself Medical Outcome Profile (MYMOP) tool at 2 weeks, 3 weeks, 4 weeks, 6 weeks, 3 months, 6 months and 24 months post-treatment intervention
3. Loss of finger extension using measuring tool (SLiCK device) at 6 weeks, and 6, 12 and 24 months post-treatment intervention
4. Adverse events and complications, recurrence of DC, and revisions or salvage surgery recorded in the Case Report Form and participant questionnaire responses up to 24 months post-treatment intervention
5. Health-related quality of life, health resource use, and cost-effectiveness assessed by a health economic analysis of health & social services costs at 2 weeks, 3 weeks 6 weeks, 6 months, 12 and 24 months post-treatment intervention

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Age >= 18 years
2. One or more fingers with a Dupuytren’s contracture of >30 with functional problems
3. No previous treatment for Dupuytren’s contracture on affected finger
4. Well defined cord(s) and suitable for NF (needle fasciotomy) or LF (limited fasciectomy)
5. Able to comply with the requirements of the study up to 24 months post-intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
406

Key exclusion criteria
1. Dupuytren’s contracture of the distal interphalangeal joints (DIP) only
2. Planned dermofasciectomy or very limited fasciectomy (excision of <1 cm cord segment)
3. Previously recruited into this study for treatment of either hand

Date of first enrolment
01/04/2021

Date of final enrolment
30/01/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Southampton General Hospital
Coxford Road
Southampton
United Kingdom
SO16 5YA

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
United Kingdom
OX3 7HE

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
United Kingdom
SO22 5DG

Study participating centre
Glasgow Royal Infirmary
84 Castle St
Glasgow
United Kingdom
G4 0SF

Study participating centre
Whiston Hospital
Warrington Road
Prescot

United Kingdom
L35 5DR

Study participating centre
Royal United Hospital Bath
Combe Park
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BA1 3NG

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Wrightington Hospital
Hall Lane
Appley Bridge
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WN6 9EP

Study participating centre
North Devon District Hospital
Raleigh Heights
Barnstaple
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EX31 4JB

Study participating centre
South Tyneside Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Great Western Hospital
Marlborough Road
Swindon
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SN3 6BB

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
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LE1 5WW

Study participating centre
Royal Blackburn Hospital
Haslingden Road
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BB2 3HH

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
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SW10 9NH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127393

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/06/2024	20/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes