

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

<b>Submission date</b> 19/08/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/02/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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 fasciectomy. 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](http://www.nottingham.ac.uk/hand1)

## **Contact information**

#### **Type(s)**

Scientific

#### **Contact name**

Mrs Eleanor Harrison

#### **ORCID ID**

<http://orcid.org/0000-0003-0652-3980>

#### **Contact details**

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Derby Road  
Nottingham, Nottinghamshire  
United Kingdom  
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  $>30^\circ$  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?
<a href="#">Protocol article</a>	protocol	25/08/2017		Yes	No
<a href="#">Results article</a>	results	30/01/2020	06/02/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No