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Flexor injury rehabilitation splint trial

Submission date
13/07/2022

Recruitment status
No longer recruiting

Registration date
20/07/2022

Overall study status
Completed

Last Edited
03/05/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English Summary
Background and study aims
Flexor tendons attach to the muscles in our forearms and give us the ability to bend our fingers. In the UK, more than 7000 people a year cut their flexor tendons. Without surgery to repair the tendons, the fingers would never bend and our hands would become useless. Following surgery, a 'made-to-measure' splint is needed to prevent the repaired tendon from re-rupturing. However, people who have had this operation have told us that wearing a splint is awkward and often means they can not work. They also told us that sometimes they do not wear their splint at all. There are currently three splints available on the NHS: long, short and mini. We do not know which of the three splints is best. The aim of the FIRST study is to determine which splint gives people the best chance of getting back their normal hand use, what is it like to wear each splint, if people wear these as instructed, and whether one splint is better value for money.

Who can participate?
Patients aged 16 years and over who have undergone a zone I/II flexor tendon repair

What does the study involve?
Participants will be randomised into 3 groups and given either the long, short or mini splint following their surgery. They will be monitored for a year. We will ask questions about their hand and wrist use and how long they had off work. We will measure how much they can move their hand and how strong their hand is. We will also ask if they have any pain in their hand or wrist, or had any other troubles because of their injury. We will put heat sensors in each splint which will monitor how much they are wearing their splint and each patient will be surveyed to find out what aspects of wearing the splint are important to them. Alongside this, we will interview 20 patients and ask them what it was like to wear the splint, we will ask if they removed their splint and why this was. We will investigate the number of appointments people have had and if they needed any extra operations or treatments to fix their hands. All of this information will be used to understand which splint is best clinically and provides the best value for money.

What are the possible benefits and risks of participating?
The study is providing information in this area as participants will be contributing to important research that will inform treatment choices for patients in future. They will be under close follow-up contact which is normal for those taking part in a research study. All flexor tendon repair patients will have a splint to wear during rehabilitation, whether or not they participate in the study. Splints have the potential risk to be uncomfortable and can cause skin irritation and

stiffness. Participants will be provided with site-specific contact details in case they experience any problems with their splint.

Where is the study run from?
University of Sheffield Clinical Trials Research Unit (United Kingdom)

When is the study starting and how long is it expected to run for?
January 2022 to May 2025

Who is funding the study?
National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) (United Kingdom)

Who is the main contact?
Hannah Berntsson (United Kingdom)
h.berntsson@sheffield.ac.uk

Study website
https://pulvertafthandcentre.org.uk/first-study/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310986

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52908, IRAS 310986

Study information

Scientific Title
Prospective randomised controlled trial comparing three splints for finger flexor tendon repairs (FIRST study).

Acronym

FIRST

Study hypothesis
The trial hypothesis is that any one of the splints may be superior, in terms of the mean post-randomisation scores (based on data collected at 6, 12, 26, and 52 weeks) for self-reported wrist /hand pain and functioning outcomes, to any of the others.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2022, South West - Cornwall & Plymouth Research Ethics Committee (Ground Floor Temple Quay House, 2 The Square, Bristol, BS1 6PN; +44(0)207 104 8071; cornwallandplymouth.rec@hra.nhs.uk), ref: 22/SW/0074

Study design
Parallel-group superiority analyst-blind multi-centre individual participant-randomized 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

Condition
Injuries and accidents

Interventions
The trial will be conducted in approximately 20 hospitals. Patients listed for, or who have undergone surgical repair of zone I/II flexor tendons will be identified from hand clinics/ theatre or hand therapy services and provided with study information. Potentially eligible patients will be given information sheets by delegated site staff and invited to consent at their first clinic visit post-surgery. Recruitment posters and/or business cards directing potential participants to the study website, where the PIS will be available online, will also be available in hand clinics at participating sites.

Participants will be randomised to receive either the long, short, or mini splint and will be followed up at 6, 12, 26 and 52 weeks post-randomisation. All follow-up visits will take place in the clinic, with the exception of the 52-week visit which will be done remotely.

The Patient-Reported Wrist and Hand Evaluation (PRWHE) questionnaire (primary outcome) will be completed at each follow-up visit. The PRWHE is a 15-item patient-reported outcome for assessing wrist and hand pain/disability on a scale of 0 to 100. The primary outcome will be the mean post-randomisation total PRWHE score. Participants will also be asked to complete questionnaires about their hand and wrist function, general health, quality of life and work productivity and activity. Participants will be asked about any adverse events at each follow-up visit. Range of movement and grip strength will be assessed by site staff blinded to treatment allocation, range of movement at baseline, 6, 12 and 26 weeks and grip strength at 12 and 26 weeks.

The project also includes a process evaluation sub-study, which will explore how patient preferences for splint attributes and patient-reported acceptability of splints influence splint adherence. This aspect will involve a survey on participant preferences (stated preferences) at baseline, and on 'revealed' preferences and acceptability of splints at 6 weeks. To understand determinants of nonadherence to the different splints and their associated harm-benefit profiles, 20 partially-nested semi-structured interviews will be conducted, sampling based on splint type and known influential factors such as employment type and dependence on vehicle use. Interviews will be audio-recorded, transcribed and analysed using qualitative techniques. Temperature sensors will be inserted into splints to measure
adherence to splint prescription.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Mean post-randomisation total score measured using the Patient Reported Wrist and Hand Evaluation (PRWHE) questionnaire at 6, 12, 26 and 52 weeks post-randomisation

Secondary outcome measures
1. Patient-reported outcomes:
1.1. Level of care received, function, pain and wellbeing measured using the Patient Evaluation Measure (PEM) at baseline, 6, 12, 26 and 52 weeks
1.2. Work productivity and activity impairment (WPAI) score measured at baseline, 6, 12, 26 and 52 weeks
1.3. Quality of life measured using the EuroQoL EQ-5D-5L questionnaire at baseline, 6, 12, 26 and 52 weeks
1.4. Details of any litigation/compensation for injury measured using a study-specific, single-item patient-reported questionnaire at 52 weeks
1.5. Change in general health measured using the global rating of change questionnaire at 6, 12, 26 and 52 weeks
1.6. Preferences for splint attributes (stated and revealed) and splint acceptability measured using study-specific surveys at baseline and 6 weeks

2. Clinical outcomes:
2.1. Range of movement measured using a goniometer and calculated as a Strickland score at

baseline, 6, 12 and 26 weeks
2.2. Grip Strength measured using the GripAble tool at 12 and 26 weeks
2.3. Adherence to the splinting protocol measured using a temperature sensor inserted into the participants' splint at baseline and removed at splint removal, at 6 weeks
2.4. Complications and adverse events measured via case report forms completed by site staff throughout participant follow-up

Overall study start date
01/01/2022

Overall study end date
22/03/2025

Eligibility

Participant inclusion criteria
1. Aged 16 years old and over
2. Primary repair of zone I/II finger flexor tendon
3. Surgical repairs according to BSSH guidelines

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 429; UK Sample Size: 429

Total final enrolment
430

Participant exclusion criteria
1. Patients with associated fractures requiring fixation or additional splintage
2. Tendon lacerations involving 3 or more fingers
3. Revascularization surgery and/or digital nerve reconstructions requiring a nerve graft
4. Presented for treatment more than 3 weeks following the original injury
5. Patients unable to consent or comply with the rehabilitation regime, for example, due to cognitive, psychological or physical disabilities
6. Co-enrolment in another hand trial

Recruitment start date
22/08/2022

Recruitment end date
22/03/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Royal Derby Hospital (nuh)
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Swansea Bay University Local Health Board
One Talbot Gateway, Seaway Drive
Seaway Parade Industrial Estate
Baglan
Port Talbot

United Kingdom
SA12 7BR

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Preston Acute Hospitals NHS Trust
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Northampton General Hospital NHS Trust
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
Amersham Hospital
Whielden Street
Amersham
United Kingdom
HP7 0JD

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
St Thomas' Hospital (alliance Medical Scanning)
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Walsgrave General Hospital
Clifford Bridge Road
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United Kingdom
CV2 2DX

Study participating centre
Queen Victoria Hospital NHS Foundation Trust
Holtye Road
East Grinstead
United Kingdom
RH19 3DZ

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
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SY3 8XQ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney

Norwich
United Kingdom
NR4 7UY

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
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E1 2ES

Study participating centre
North Bristol NHS Trust
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Southmead Road
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Bristol
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BS10 5NB

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0AU

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton

Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Sponsor information

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University Hospitals of Derby and Burton NHS Foundation Trust

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Royal Derby Hospital
Uttoxeter Road
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United Kingdom
DE22 3NE
+44 (0)1332 724639
Uhdb.sponsor@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.uhdb.nhs.uk/

ROR
https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name

National Institute for Health and Care Research; Grant Codes: NIHR133582

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
1. Planned publication in a high-impact peer-reviewed journal
2. Conference presentation
3. Publication on website
4. Submission to regulatory authorities

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2.2	29/06/2023	03/11/2023	No	No
Protocol article		16/03/2024	18/03/2024	Yes	No