

# FLexor repAir and REhabilitation (FLARE) Trial

<b>Submission date</b> 07/10/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/01/2023	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 06/03/2026	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A deep cut through the fingers is a common injury that damages the flexor tendons. They are smooth cords that help the fingers to bend. There are two flexor tendons in each finger, which join the muscles in the forearm to the bones in the fingers. One tendon bends the middle knuckle, the other bends the fingertip. Flexor tendon injuries to the finger are more common in young adults. The usual treatment is an operation to stitch the severed tendon ends together, followed by 12 weeks of rehabilitation. There is low-quality evidence as to whether repairing both tendons is better than one tendon alone. In order to generate good quality evidence that can guide practice, the repair of one tendon alone needs to be formally tested in a clinical trial. The aim of this study is to conduct a two-arm randomised controlled trial comparing the repair of one tendon versus repairs of both tendons in complete zone 2 injuries.

### Who can participate?

Adult patients (who are 16 years old or older), who attend a participating hospital with an open injury in zone 2 of a single finger and where the complete division of both flexor tendons is suspected

### What does the study involve?

Participants will be randomly allocated to receive either surgery to repair one tendon only or surgery to repair both tendons. Participants will be assessed at the start of the study, then at 1 week, 6 weeks, 3 months and 6 months after surgery. Participants will be asked to complete questionnaires, and a clinical assessment of the range of motion and grip strength is undertaken. Rehabilitation will be according to routine practice at the treating hospital. A subset of participants will take part in an interview about their experiences and receiving treatment for this injury, their recovery and taking part in the research. The cost of both treatments is calculated relative to their benefits to find out which is better value for money for the NHS.

### What are the possible benefits and risks of participating?

Participants may not benefit from taking part, however, if enough people take part in this study, the information we get should help ensure that people with these injuries have informed treatment choices in the future. This study only includes interventions that are already used in the NHS. As with many medical procedures, there are some potential risks, mainly in relation to surgery and anaesthesia. Participants in both groups will undergo surgery and risk is not increased through trial participation. Flexor tendon repair patients usually have a splint to wear

during rehabilitation, whether or not they participate in the study. Splints have the potential to be uncomfortable and may cause skin irritation and stiffness.

Where is the study run from?

York Trials Unit, University of York (UK)

When is the study starting and how long is it expected to run for?

April 2022 to September 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA) Ref: 133784 (UK)

Who is the main contact?

Mr Matthew Gardiner, matthew.gardiner@nhs.net (UK)

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Liz Cook

### ORCID ID

<https://orcid.org/0000-0001-6902-0235>

### Contact details

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### Type(s)

Principal investigator

### Contact name

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### **Type(s)**

Principal investigator

### **Contact name**

Dr Emma Reay

### **Contact details**

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## **Additional identifiers**

### **Integrated Research Application System (IRAS)**

316277

### **Central Portfolio Management System (CPMS)**

54953

## **Study information**

### **Scientific Title**

A randomised trial to determine the clinical and cost-effectiveness of repairing flexor digitorum profundus (FDP) alone versus repair of both FDP and flexor digitorum superficialis (FDS) for treatment of complete zone 2 flexor tendon injuries: the FLeXor repAir and 'REhabilitation (FLARE) Trial

### **Acronym**

FLARE

### **Study objectives**

Flexor digitorum profundus (FDP) repair alone is not inferior to FDP and flexor digitorum superficialis (FDS) repair for the treatment of recent complete zone 2 flexor tendon injuries in adults based on the patient reported outcome Patient Evaluation Measure (PEM) at 6-months post-randomisation.

### **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 07/03/2023, North West - Greater Manchester Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 1048191; gmcentral.rec@hra.nhs.uk), ref: 23/NW/0004

## **Study design**

Multicentre two-arm parallel-group non-inferiority randomized controlled trial with an internal pilot economic evaluation and nested qualitative study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Traumatic injury to the hand in zone 2 injuries causing the flexor digitorum profundus and flexor digitorum superficialis to be severed.

## **Interventions**

Main FLARE trial

The intervention is repair of flexor digitorum profundus (FDP) alone, compared to the usual practice of the repair of FDP and flexor digitorum superficialis.

Participants will undergo treatment as per the randomisation allocation schedule under the care of one of the participating surgeons

Associate PI Study Within A Trial (API SWAT)

A 2x2 factorial SWAT embedded in the main trial utilising the NIHR API Scheme. All sites recruiting to FLARE who have a confirmed Associate PI (API) will be included. Aim is to evaluate the effect on recruitment rates of using two interventions: Enhanced Associate Principal Investigator Package and Digital Nudging on participant recruitment rates.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Main FLARE trial

Patient assessment of treatment, hand health and overall hand assessment, measured using a Patient Evaluation Measure (PEM) at 6 months post-surgery

## **Key secondary outcome(s)**

Main FLARE trial

1. Patient assessment of hand/wrist pain and disability in activities of daily living, measured using the Patient Related Wrist/Hand Evaluation (PRWHE) at baseline, 6 weeks, 3 months and 6 months post-surgery
2. Quality of life measured using the EQ-5D-5L questionnaire at baseline, 6 weeks, 3 months and 6 months post-surgery
3. Complications and Adverse Events collected by patient-reported questionnaires and review of hospital records up to 6 months post-surgery
4. Total range of motion, measured using a goniometer at 6 weeks and 3 months post-surgery

5. Grip strength measured using a dynamometer at 3 months post-surgery
6. Adherence to the splint regimen measured using patient self-report at 6 weeks post-surgery
7. Work outcomes measured using patient self-report at 6 weeks, 3 months and 6 months post-surgery
8. Treatment and outcome satisfaction measured using a net promoter score and PEM at 6 weeks, 3 months and 6 months post-surgery
9. Healthcare resource use measured patient self-report and medical records at surgery, up to 1 week, 6 weeks, 3 months and 6 months post-surgery
10. Adherence to the therapy regimen measured using patient self-report at 6 weeks and 3 months post-surgery

**Completion date**

30/09/2026

## Eligibility

**Key inclusion criteria**

Inclusion criteria for screening:

1. Patients aged 16 years old and over

Inclusion Criteria for randomisation (confirmed in surgery):

2. Complete division of FDP and FDS in zone 2 of a single finger
3. Injury amenable to primary repair

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Upper age limit**

110 years

**Sex**

All

**Total final enrolment**

43

**Key exclusion criteria**

Eligibility criteria for screening:

1. Injuries affecting more than one digit or the thumb
2. Injuries outside of Zone 2
3. Injuries affecting multiple zones

4. Clinically infected wounds
5. Closed flexor tendon injury
6. Previous tendon, bone or joint injury in the affected digit
7. Patient does not have capacity to give informed consent
8. Patient unable to complete follow-up requirements
9. Contraindications to surgery

Exclusion criteria for randomisation (confirmed at surgery):

10. Injuries with loss of tendon substance or skin necessitating reconstruction
11. Division of both digital arteries resulting in revascularisation of injured digit
12. Division of both digital nerves

**Date of first enrolment**

23/08/2023

**Date of final enrolment**

30/04/2025

## **Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**

**Wexham Park Hospital**

Wexham Street

Wexham

Slough

England

SL2 4HL

**Study participating centre**

**James Cook University Hospital**

Marlon Road

Middlesbrough

England

TS4 3BW

**Study participating centre**  
**Leeds General Infirmary**  
Great George Street  
Leeds  
England  
LS1 3EX

**Study participating centre**  
**North Cumbria University Hospitals NHS Trust**  
Cumberland Infirmary  
Newtown Road  
Carlisle  
England  
CA2 7HY

**Study participating centre**  
**Basingstoke and North Hampshire Hospital**  
Aldermaston Road  
Basingstoke  
England  
RG24 9NA

**Study participating centre**  
**Royal Cornwall Hospital (treliske)**  
Treliske  
Truro  
England  
TR1 3LJ

**Study participating centre**  
**Stoke Mandeville Hospital**  
Mandeville Road  
Aylesbury  
England  
HP21 8AL

**Study participating centre**  
**St George's University Hospitals NHS Foundation Trust**  
Blackshaw Rd  
London

England  
SW17 0QT

**Study participating centre**

**Queen Elizabeth Hospital**

University Hospitals Birmingham NHS Foundation Trust  
Mindelsohn Way  
Edgbaston  
Birmingham  
England  
B15 2GW

**Study participating centre**

**Royal Victoria Infirmary**

The Newcastle upon Tyne Hospitals NHS Foundation Trust  
Queen Victoria Road  
Newcastle upon Tyne  
England  
NE1 4LP

**Study participating centre**

**University Hospital of North Durham**

University Hospital of Durham  
Dryburn Hospital  
North Road  
Durham  
England  
DH1 5TW

**Study participating centre**

**Peterborough City Hospital**

North West Anglia NHS Foundation Trust  
Bretton Gate  
Bretton  
Peterborough  
England  
PE3 9GZ

**Study participating centre**

**Addenbrookes Hospital**

Hills Road

Cambridge  
England  
CB2 0QQ

**Study participating centre**

**North Tyneside General Hospital**

Northumbria Healthcare NHS Foundation Trust  
Rake Lane  
North Shields  
England  
NE29 8NH

**Study participating centre**

**Lister Hospital**

East and North Hertfordshire NHS Trust  
Coreys Mill Lane  
Stevenage  
England  
SG1 4AB

**Study participating centre**

**Hull Royal Infirmary**

Hull University Teaching Hospitals NHS Trust  
Anlaby Road  
Hull  
England  
HU3 2JZ

**Study participating centre**

**John Radcliffe Hospital**

Oxford University Hospitals NHS Foundation Trust  
Headley Way  
Headington  
Oxford  
England  
OX3 9DU

**Study participating centre**

**Forth Valley Royal Hospital**

Stirling Road  
Larbert

Scotland  
FK5 4WR

**Study participating centre**

**Royal Derby Hospital**

University Hospitals of Derby and Burton NHS Foundation Trust  
Uttoxeter Road  
Derby  
England  
DE22 3NE

**Study participating centre**

**Morrison Hospital**

Heol Maes Eglwys  
Cwmrhydyceirw  
Swansea  
Wales  
SA6 6NL

**Study participating centre**

**Chelsea & Westminster Hospital**

Chelsea and Westminster Hospital NHS Foundation Trust  
369 Fulham Road  
London  
England  
SW10 9NH

**Study participating centre**

**Queen Victoria Hospital NHS Foundation Trust**

Holtye Road  
East Grinstead  
England  
RH19 3DZ

## **Sponsor information**

**Organisation**

South Tees Hospitals NHS Foundation Trust

ROR

<https://ror.org/02js17r36>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study (fully anonymised) will be available upon request after the publication of the study results from Prof. Catherine Hewitt ([catherine.hewitt@york.ac.uk](mailto:catherine.hewitt@york.ac.uk)).

Participants will be informed that information collected about them may be shared anonymously with other researchers and will be asked to consent to this.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		21/10/2025	24/10/2025	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	28/04/2025	01/05/2025	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	14/04/2025	01/05/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes