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FLexor repAir and REhabilitation (FLARE) Trial

Submission date
07/10/2022

Recruitment status
No longer recruiting

Registration date
12/01/2023

Overall study status
Ongoing

Last Edited
01/05/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 July 2025

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)

Study website
https://www.flaretrial.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316277

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 316277, 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

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 participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/04/2022

Completion date
31/07/2025

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

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
310

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
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Wexham Park Hospital
Wexham Street

Wexham
Slough
United Kingdom
SL2 4HL

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

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

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

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

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

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

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Rd
London
United Kingdom
SW17 0QT

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

Study participating centre
Royal Victoria Infirmary
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
University Hospital of North Durham
University Hospital of Durham
Dryburn Hospital
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
Peterborough City Hospital
North West Anglia NHS Foundation Trust
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Lister Hospital
East and North Hertfordshire NHS Trust
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Hull Royal Infirmary
Hull University Teaching Hospitals NHS Trust
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre

John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

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

Study participating centre

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

Study participating centre
Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust
Kayll Road
Sunderland
United Kingdom
SR4 7TP

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

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

Sponsor details
STRIVE Academic Centre
The James Cook University hospital
Middlesborough
England
United Kingdom
TS4 3BW
+44 (0)1642850850
dtvra.projects@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://southtees.nhs.uk/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A dissemination and publication policy will be developed with an agreement between partners including ownership and exploitation of intellectual property, and publication rights. The publication policy and the agreement will ensure that any intellectual property generated during the project is protected and that the publication process is organised in a fair, balanced and transparent manner. The TMG will be responsible for overseeing these arrangements. The creation and signature of the agreements will be the responsibility of the coordinating centre (University of York). It will be ensured that all partners have input into the document.
Targets for dissemination will include NICE, Clinical Commissioning Groups, the Department of Health and the Speciality Advisory Committees (SAC) for the curriculum for clinicians who will undertake treatment of flexor tendon repairs. The study protocol and results will be presented orally and will be made publicly available in appropriate publications and a summary of the study will be made available in plain English for patient-focused outlets.
The executive summary and copy of the trial report will be sent to NICE and other relevant bodies, including Clinical Commissioning Groups, so that the study findings can inform their deliberations and be translated into clinical practice nationally. We will also work with the relevant National Clinical Director in the Department of Health to help ensure the findings of the trial are considered when implementing policy and will work with the Speciality Advisory Committees (SAC) to incorporate the findings into the training curriculum for clinicians who will undertake treatment of flexor tendon injuries. A number of dissemination channels will be used

to inform clinicians, patients and the public about the results of the study. The projected outputs are listed below.
We will seek to raise the profile of the trial via social media including a dedicated Twitter account. This will be aimed at participating site staff and focus on trial progress, trial related events, and publicising research outputs.
The study protocol will be published in a peer-reviewed, open access journal, after the study commences.
A HTA monograph will be produced.
On completion of the study, the findings of the HTA report will be presented at national and international meetings such as the International Federation of Societies for Surgery of the Hand (IFSSH) and Hand Therapy (IFSHT).
The study report will be published in peer reviewed high impact general medical, surgical and hand therapy journals; such as Lancet, the BMJ, the Journal of Hand Surgery (European), Hand Therapy or Journal of Hand Therapy.
The study results will be shared with relevant evidence synthesis teams (including within the Cochrane Collaboration) in order to ensure that results are incorporated in future systematic reviews.
A summary of the study report, written in lay language will be produced and made available to participants, members of our user group and relevant patient-focused websites. As part of the trial an information booklet on the condition, the likely recovery process and hand exercises will be produced. We will explore making this more widely available to patients following the trial.
The findings of the SWAT will be disseminated in a relevant journal read by trialists such as BMC Trials and disseminated at relevant conferences such as the International Clinical Trials Methodology Conference. Data will be made available to allow for inclusion in future meta-analyses with studies of the same intervention in other trials.

Intention to publish date
31/01/2026

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).
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?
HRA research summary			26/07/2023	No	No
Statistical Analysis Plan	version 1.0	28/04/2025	01/05/2025	No	No
Statistical Analysis Plan	version 1.0	14/04/2025	01/05/2025	No	No