



# Associate Principal Investigator (API) Induction

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## Sponsor

South Tees Hospitals NHS Foundation Trust



South Tees Hospitals  
NHS Foundation Trust

## Co-Chief Investigators

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## Statistician

Kalpita Baird

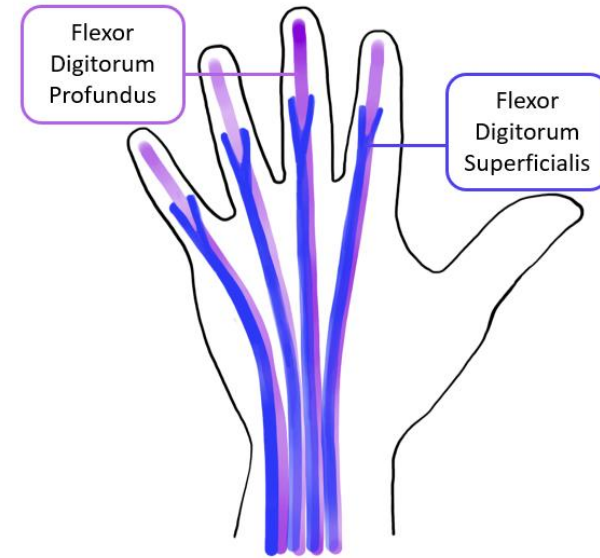


## Qualitative Lead

Arabella Scantlebury



- When both FDP and FDS flexor tendons have been severed within zone 2, the repair is technically difficult and there is a higher risk of scar tissue forming between the flexor tendons.
- Service evaluations have demonstrated that there is no consensus among surgeons as to whether FDP and FDS should be repaired, or just FDP alone.
- Both surgical treatments are currently being practiced throughout the NHS.
- A randomised controlled trial is required to inform clinical practice of whether the repair of FDP alone is as beneficial to the patient as the repair of FDP and FDS.



## Primary Hypothesis

FDP repair alone is not inferior to FDP and 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.

## Primary Objective

The primary objective is to ascertain the clinical and cost effectiveness of repairing FDP alone versus repair of both FDP and FDS for treatment of complete zone 2 flexor tendon injuries in adults aged 16 years and above.

## Secondary Objectives

- Undertake an 8 month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility.
- Assess range of motion and grip strength.
- Compare the complications of both types of repair.
- Assess and compare Patient Related Wrist/Hand Evaluation.
- Comparison of costs, quality adjusted life years and cost effectiveness of both interventions (repairing FDP alone or both FDP and FDS).
- Undertake an embedded qualitative study.

**Study Design:** Multi-centre, two-arm, blinded, non-inferiority, parallel group, randomised controlled trial with an internal pilot, economic evaluation and nested qualitative study.

**Two arms:** Repair of FDP alone vs repair of FDP and FDS.

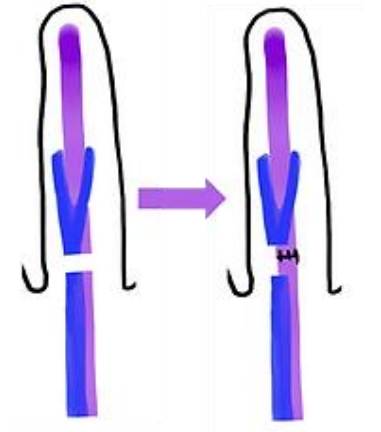
**Setting:** Participating Hand Trauma Centres within the UK treating flexor tendon injuries and with facilities to support research activity.



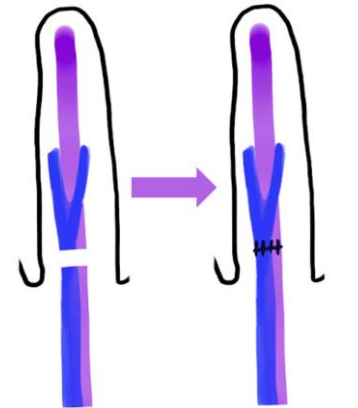
**Sample Size:** 310 (155 in each arm).



**Number of Sites:** up to 40.



Repair of Flexor Digitorum  
Profundus alone



Repair of Flexor Digitorum  
Profundus and Flexor Digitorum  
Superficialis

- Speciality Trainees in Trauma and Orthopaedic Surgery or AHPs can sign up.
- Primary role is to coordinate local trainee involvement in identifying, consenting and randomising patients to the study.
- Also act as a source of information, advice and train others regarding trial procedures locally.
- APIs work with local PI to help to coordinate recruitment of patients, particularly out of hours.
- A commitment of six months will be required for gaining API status.
- NIHR has also put together an API Toolkit to serve as guidance documents

(<https://sites.google.com/nihr.ac.uk/associatepiscHEME/toolkits/associate-pi-toolkit>)

- Collaborator Status can be achieved based on points outlined in the FLARE Trial Site Manual.
- Evidence as Leadership & Management requirement for ARCP and CCT.
- Evidence as Research requirements for ARCP and CCT.
- Experience in a trial that can be used in your future career to become a local Principal Investigator.

- GCP is the agreed international standard for conducting clinical research.
- Protects the rights and safety of people taking part in research studies and enables you to collect reliable research data.
- Needed for researchers conducting Clinical Trials of Investigational Medicinal Products (CTIMPs) and some non-CTIMPs.
- Types of training available
  - Introduction
  - Refresher
- E-learning or face to face workshops available to book via NIHR Learn.
- Provided with a GCP Training Certificate following completion.
- Certificate is usually valid for 2-3 years (depending on Trust/employer policy).
- GCP courses are CPD accredited, see NIHR Learn for further details.



- GRANULE (**GeneRAtiNg sUrgical rEcruiters** for randomised trials)

<https://www.nihr.ac.uk/explore-nihr/specialties/surgery.htm>

Designed to equip researchers with the practical skills to recruit patients into randomised surgical trials.

By completing the course, you will

- Understand why we need randomised controlled surgical trials.
- Understand how to convey clinical equipoise, explain randomisation and address patient preferences.
- Be able to successfully recruit to randomised controlled trials in surgery.

- Informed consent

Informed consent is covered by GCP Training, however additional courses are available (via NIHR Learn) regarding

- Informed consent with different communities.
- Informed consent: including adults lacking capacity.
- Informed consent with children.
- Remote consent.

**Please review NIHR Learn for any other courses you may be interested in.**

- CV needs to demonstrate that you are qualified by education, training and experience to conduct the research.
- Should be concise, ideally to around two pages.
- Not necessary to provide a complete record of your professional and academic background.
- Requested from Principal Investigators (as a minimum, may be requested from other site research team members also).
- <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/>

## CURRICULUM VITAE

<b>Name:</b>	
<b>Present appointment:</b> <i>(Job title, department, and organisation.)</i>	
<b>Address:</b> <i>(Full work address.)</i>	
<b>Telephone number:</b>	<b>Email address:</b>
<b>Qualifications:</b>	
<b>Professional registration:</b> <i>(Name of body, registration number and date of registration.)</i>	
<b>Previous and other appointments:</b> <i>(Include previous appointments in the last 5 years and other current appointments.)</i>	
<b>Research experience:</b> <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i>	
<b>Research training:</b> <i>(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)</i>	
<b>Relevant publications:</b> <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i>	
<b>Signature:</b>	<b>Date:</b>

- Supporting delivery of the FLARE Site Initiation Visit (e.g., helping to arrange/coordinate the meeting at site).
- Complete FLARE Trial training and be listed on the study delegation log.
- Familiarise yourself with the eISF and trial documentation requiring completion.
- Disseminate information about the study to others (e.g., display trial posters in staff areas, present details of the trial at a departmental meeting, make yourself known to others as the FLARE Trial API).
- Arrange/attend regular meetings with the site research team to discuss trial delivery (such as recruitment progress, data queries, protocol amendments etc.).
- Maintain a diary of research team meetings (expected to be at least monthly).
- Frequently review the delegation log to ensure this is up to date with all site team members.
- Help to ensure all delegated team members are trained in the protocol requirements and study procedures (e.g., signpost and discuss the FLARE Trial protocol, Trial Site Manual and Study Specific Training with new team members).
- Ensure the Screening & Eligibility instrument is completed on REDCap for all patients screened.

- Screen, recruit and consent a patient (if delegated to do so by PI) and complete all necessary documentation
- Complete a follow-up visit (if delegated to do so by PI, consider blinding arrangements at site)

- Attending investigator meetings delivered by the central FLARE trial management team.
- Engage in patient and public involvement (PPI) activities (e.g., displaying trial posters in patient areas).
- Regular email correspondence with York Trials Unit.
- Interacting with other APIs (e.g., via Associate PI forum on NIHR).

***These activities are not mandatory for Associate PI status.***

# Thank you for your time.

## Any questions?

*Alternatively, please...*

 *contact us on the FLARE Trial email address: [ytu-flare-trial@york.ac.uk](mailto:ytu-flare-trial@york.ac.uk)*

 *follow us for the latest FLARE trial news: [@FLARE\\_\\_Trial](https://twitter.com/FLARE__Trial)*

 *go to the FLARE Trial Website: [www.flaretrial.com](http://www.flaretrial.com)*

 *join the all-site FLARE WhatsApp group*

