



## Simple Olecranon Fracture Fixation Trial

## Associate Principal Investigator (API) Induction

# TRIAL PROJECT TEAM

➤ **Chief Investigator:**

Professor Adam Watts (Wrightington, Wigan and Leigh NHS Foundation Trust)

➤ **York Trials Unit**

Trials Unit Director: Professor David Torgerson

Trial Manager: Liz Cook

Trial Coordinators: Sophie James and Zohaib Ahkter

Trial Statistician: Danielle Podmore

Health Economist: Belen Corbacho

# BACKGROUND AND RATIONALE

- Currently, displaced fractures of the olecranon with a stable ulnohumeral joint are commonly managed by open reduction to realign the fractured bone fragments and internal fixation with tension band wiring.
- A complication after fixation with tension band wiring is that the metalwork causes discomfort or breaks through the skin. A second surgery, with the associated surgical risks and delayed recovery for patients and costs for the NHS, is frequently required.
- An alternative approach is to fix the fracture using strong synthetic sutures alone. Tension suture repair is considered less likely to require a second surgery to remove the fixation material, thereby reducing risk and inconvenience for the patient and saving the NHS money, without compromising the outcome.
- However, there is no high quality evidence from a randomised controlled trial (RCT) to determine whether the functional outcome of the tension suture repair is non-inferior to tension band wiring in restoring patient function and provides sufficient benefit to patients and the NHS in terms of reduced second surgeries

# SOFFT OBJECTIVES

## Primary objective

- To undertake a multi-centre parallel group RCT to determine whether tension suture repair is not inferior to traditional tension band wiring for the internal surgical fixation of Mayo Grade IIA fractures of the olecranon in adult patients over the age of 16 years.

## Secondary objectives

- Undertake a 9-month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility.
- To undertake an analysis of the rate of re-operation.
- To investigate the cost-effectiveness of the two interventions from the NHS perspective in order to identify the most efficient provision of future NHS care and to describe the resource impact on the NHS for the two treatment options.

# TRIAL DESIGN

## ➤ METHOD

A large pragmatic, two-arm, open, parallel group, individually randomised, controlled trial.

## ➤ POPULATION

Adults (males and females) aged 16 years and over with a clinical diagnosis of a Mayo Grade IIA acute olecranon fracture requiring surgical fixation.

## ➤ INTERVENTION: Tension suture repair

## ➤ CONTROL: Standard tension band wiring

## ➤ SAMPLE SIZE: 280 (140 in the intervention group and 140 in the control group)

## ➤ SITES: 35

# OUTCOME MEASURES

## Primary

- Disabilities of the Arm Shoulder and Hand (DASH) score at 4 months follow-up.

## Secondary

- DASH (at 12, 18, and 24 months),
- Pain score
- EuroQol 5 Dimensions (5L) Score (EQ5D-5L)
- Radiological union
- Complications
- Elbow range of movement
- Resource use and work impact
- Re-operations related to the injury or to remove metalwork

# INTERVENTION

## TENSION SUTURE REPAIR TECHNIQUE

- The mandatory, prohibited and optional elements of the tension suture repair intervention are defined as the following; accurate fracture reduction, compression with a clamp, a transverse 2.5mm drill hole placed in the ulna distal to the fracture site (no less than 2mm, no more than 3.5mm), repair with two lengths of Number 2 synthetic braided suture passed through the drill hole and the insertion of triceps to the olecranon (no less than 2 sutures, more than two sutures can be use up to a maximum of 4, suture material should be Orthocord, Fibrewire or Fibretape (Vicryl, Ticron or Ethibond should not be used), suture size not less a No.2 and not greater than No.5), a minimum of two sutures should be configured according to technique of Das, Jariwala and Watts, sutures must be passed through the triceps tendon at the insertion to the olecranon, suture knots should be buried under Anconeus muscle and no supplementary k-wires should be used.
- Mandatory training in the technique is provided to site PIs who are requested to cascade this at site.

# CONTROL

## TENSION WIRE BANDING

- This will be undertaken according to standard AO technique using two longitudinal K-wires and one or two steel cerclage wires in a figure of eight configuration to provide compression through a transverse 2.5mm drill hole in the ulna distal to the fracture site. All participating surgeons will be invited to a training course to revise the standard AO technique of tension band wiring of the olecranon and the ten criteria established by Schneider for optimal technique.

# INCLUSION CRITERIA

- Male or Female patients aged  $\geq 16$  years
- Mayo Grade IIA acute fracture within 3 weeks of injury
- Closed or Gustillo and Anderson grade 1 open injury
- The surgeon believes the patient will benefit from surgical intervention
- Ability to give informed consent



# EXCLUSION CRITERIA

- Surgery contra-indicated
- Gustillo and Anderson grade 2 or 3 open injury
- Associated upper limb injuries or prior upper limb pathology adversely affecting function
- Evidence of fracture comminution (Mayo Grade IIB) or instability around the elbow and/or forearm (Mayo Grade III)
- Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires
- Previous entry into SOFFT
- Concurrent olecranon fracture in the opposite limb



# THE API ROLE

- A specially nominated trainee who works with the local consultant PI
- 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 trainees regarding trial procedure locally
- Ensure that you are GCP trained and have an up to date research CV

# API SUGGESTIONS

- Introduce yourself to the local Principal Investigator and the Orthopaedic Research nurses
- Familiarise yourself with the location of the SOFFT Investigator Site file
- Familiarise yourself with the trial documentation that need to be completed
- Make yourself known to the department (consultants and trainees) as the SOFFT API
- Organise a research induction with trainees and research nurse for patient recruitment guidance
- Ensure that everyone has GCP and facilitate GCP training for those who do not have it
- Targeted reminders to colleagues to recruit to SOFFT prior to on call shifts.
- Attend trauma meetings or delegate this responsibility in order go find eligible patients
- Liaise with research nurses regularly to review recruiting performance

# API BENEFITS

- Collaborator on trial publication
- 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 consultant career to become a local Principal Investigator

# CONSENT PROCEDURE

- It is expected that the API will facilitate eligibility confirmation by the treating clinician (i.e. Eligibility form sign off by the consultant surgeon on delegation log) before initiating the trial recruitment process.
- Eligible patients will then be approached for voluntary, informed consent for the trial. The consent process will be coordinated by the site research team that has formal delegated duties to obtain consent for the trial.
- Patients who lack mental capacity will not be eligible for participation in this trial.
- The PI, delegated consultants, API or a designated ST colleague trained in the trial procedures and on the delegation log may perform this task if required when treatment is scheduled to be carried out before a research nurse is available to take consent.

**Please refer to Trial Procedure Manual – Consent guidance and FAQs**

# RANDOMISATION

- The research team at each study site will have access to the system to complete randomisation following participant consent and completion of Baseline assessments and documentation. The Screening ID number is required for randomisation and will continue to be used to identify the participant through the study.
- Randomisation is carried out via the internet using a secure, central randomisation service hosted by York Trials Unit.
- The randomisation system will allocate participants 1:1 to one of the two study arms (Tension wire banding or tension suture repair).
- Clinicians will be unblinded to study treatment allocation. Participants are BLIND to study treatment.

**Please refer to Trial Procedure Manual – Completing Participant Randomisation for further information**

# KEY CONTACTS

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