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A comparison of two methods of surgical fixation for the treatment of simple olecranon fractures in adults

Submission date
11/05/2020

Recruitment status
No longer recruiting

Registration date
19/05/2020

Overall study status
Completed

Last Edited
19/06/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Fractures (a break in the bone) of the olecranon (bony point of the elbow) are common and usually happen after a fall onto the elbow. The risk of having this fracture increases as we get older. If a patient is well enough they usually have surgery to fix the fracture as a day case. Commonly the bone is held using tension band wiring technique, a metal wire bent around the bone and two smooth pins. This is effective in holding the position for the fracture to heal. However, the wires can cause pain because they lie just under the skin. One in three patients will have a second operation to remove the wires, exposing them to further surgical risks and resulting in increased costs to the National Health Service. Another way to hold the bone is to use a strong material cord (tension suture fixation). Some small studies looking at this technique have shown that this can reliably hold the bones in a good position while they heal and that the patient does not experience any discomfort from the prominence of the suture material. One small study found the need for further surgery was reduced to less than one in twenty. This is better for the patients and could save the NHS about 4 million pounds a year but a larger study is needed to confirm this finding. This study aims to compare two methods of surgical treatment for adult patients with olecranon fractures to find out which has a better patient outcome in terms of return to function.

Who can participate?
Patients aged 16 years or older who attend a participating hospital with an olecranon fracture

What does the study involve?
Participants are randomly allocated to either receive surgery using tension suture repair or tension band wiring to fix the fracture. Participants are assessed at the start of the study, then at 4, 12 and 18 months, and some participants at 2 years. Participants complete a few questionnaires, an assessment of elbow range of motion (at 4 months), and have x-rays to check healing at 4 months. 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?
Within the trial, participants allocated to receive tension suture repair may experience benefit as they may be less likely to require a second surgery to remove the fixation material, thereby reducing the risks associated with surgery and the inconvenience for the patient, though the purpose of the study is to provide evidence regarding this.
This study only includes treatments that are already used in the NHS but as with many medical procedures, there are some potential risks, mainly in relation to the surgery and anaesthesia. Most commonly, patients may experience pain around the arm. This usually improves after 48 hours or so as the body heals. Some patients feel nauseous or light-headed after surgery due to the anaesthetic, which usually passes over 24 hours. It is rare, but some people can have a bad reaction to anaesthesia. Severe allergic reactions to anaesthesia are very rare, less than 1 in 1000. Specific common risks to the tension wiring banding technique include that further surgical procedures may need to be carried out, for example, to remove the metalwork as it may be uncomfortable, move or fail. Based on clinical experience it is estimated that one in five may require removal. No specific common risks with tension suture repair technique have been identified. This is a newer technique and risks may include a need to re-operate if the fixation fails.

Where is the study run from?
Wrightington, Wigan and Leigh NHS Foundation Trust (lead site) (UK)

When is the study starting and how long is it expected to run for?
November 2019 to June 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Liz Cook
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Study website
http://www.york.ac.uk/healthsciences/research/trials/research/trials/sofft/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276873

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45217, IRAS 276873

Study information

Scientific Title
Suture fixation versus tension band wiring for simple olecranon fracture fixation: a multi-centre randomised controlled trial (Simple Olecranon Fracture Fixation Trial – SOFFT)

Acronym
SOFFT

Study objectives

The functional outcome, measured by the DASH score at 4 months, for the tension suture repair technique will not be 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/06/2020, 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), REC ref: 20/NW/0234

Study design
Randomized; Both; Design type: Treatment, Surgery, Health Economic

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
Olecranon fracture

Interventions
This is a multi-centre, randomised controlled non-inferiority trial, with an internal pilot phase to check the assumptions about recruitment and provide guidance on optimising the trial processes.

This study will be carried out in up to 35 NHS major trauma centres and Trauma Units within the UK treating olecranon fractures and with facilities to support research activity.

A total of 280 (140 in the intervention group and 140 in the control group) male and female patients will be recruited for the study.

Prior to study involvement: Patients will be given a participant information sheet to read and be given sufficient time to consider this information.

Eligible and consenting patients will be randomly allocated to either tension suture repair or standard tension band wiring. Participants will not be informed of their treatment allocation.

Intervention: fixation using tension suture repair
Control: fixation using tension band wiring

Postoperatively, patients will receive all other medical care including physiotherapy as per standard of care.

All patients randomised into the two groups will also receive standardised, written physiotherapy advice detailing suggested exercises they are to perform.

The researchers will assess outcomes at the start of the study, then at 4, 12, and 18 months and some at 24 months when participants will complete questionnaires that measure elbow function and pain. Participants will attend a clinic visit that will include x-rays to check healing at 4 months. The associated costs of both treatments to the NHS will also be evaluated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Physical function of the upper limb measured using the Disabilities of the Arm Shoulder and Hand (DASH) score at 4 months

Secondary outcome measures
Collected at 4, 12 and 18 months post-randomisation for the whole population, and at 24 months post-randomisation only for those who reach that follow-up point within the trial recruitment and follow-up window of up to month 48 of the study (unless stated otherwise):
1. Physical function of the upper limb measured using the Disabilities of the Arm Shoulder and Hand (DASH) score at 12, 18, and 24 months
2. Pain measured using a Numeric Rating Scale
3. Patient satisfaction measured using a Net Promotor Score
4. Health-related quality of life measured using EuroQol 5 Dimensions (5L) Score (EQ5D-5L). EQ-5D-5L data will be collected twice at baseline: i.e. once to assess patient health-related quality of life on the day (after the injury) and once with regard to the week before injury.
5. Radiological union measured using x-ray imaging at 4 months
6. Complications collected by patient-reported questionnaires and review of hospital records
7. Elbow range of movement (flexion, extension, pronation and supination) assessed by a suitably trained independent observer using a hand-held goniometer following trial-specific instructions at 4 months
8. Re-operations related to the injury or to remove metalwork; reason for reoperation will be recorded
9. Resource use and work impact: patient-reported questionnaires and hospital forms will be designed to collect information on hospital stay (initial and subsequent inpatient episodes, outpatient hospital visits and A&E admissions); primary care consultations (e.g. GP, nurse and physiotherapy); work impact of both interventions; and return to work and return to normal activities.

Overall study start date
01/11/2019

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Patients aged > = 16 years
2. Mayo Grade IIA acute olecranon fracture within 3 weeks of injury
3. Closed or Gustillo and Anderson grade 1 open injury
4. The surgeon believes the patient will benefit from surgical intervention
5. Ability to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 280; UK Sample Size: 280

Total final enrolment
280

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

Date of first enrolment
13/10/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust (Lead Site)
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
United Kingdom
WN6 9EP

Study participating centre
University Hospitals Of Leicester NHS Trust
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
NHS Lothian
Edinburgh Royal Infirmary
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

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

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton

United Kingdom
BN2 5BE

Study participating centre
Cardiff and Vale University Health Board
Cardiff and Vale UHB Headquarters
University Hospital of Wales (UHW)
Heath Park
Cardiff
Cardiff
United Kingdom
CF14 4XW

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

Study participating centre
Greater Glasgow Health Board
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

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

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Royal Devon & Exeter Hospital
Barrack Road

Exeter
United Kingdom
EX2 5DW

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
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SY10 7AG

Study participating centre
Tayside Health Board
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Study participating centre
Betsi Cadwaladr University Local Health Board
Ysbyty Gwynedd
Penrhos Garnedd
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United Kingdom
LL57 2PW

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

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Kings College Hospital NHS Foundation Trust
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Denmark Hill

London
United Kingdom
SE5 9RS

Study participating centre
Homerton University Hospital NHS Foundation Trust
Homerton Row
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E9 6SR

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
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Milton Keynes University Hospital NHS Foundation Trust
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Study participating centre
Liverpool University Hospitals NHS Foundation Trust
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L7 8XP

Study participating centre
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SE13 6LH

Study participating centre
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SW17 0QT

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
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SM5 1AA

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

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
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CH49 5PE

Study participating centre
Hampshire Hospitals NHS Foundation Trust
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Aldermaston Road
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United Kingdom
RG24 9NA

Study participating centre
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Portsmouth Road
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GU16 7UJ

Study participating centre
Maidstone & Tunbridge Wells NHS Trust
The Tunbridge Wells Hospital
Tonbridge Road
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TN2 4QJ

Study participating centre
The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust
Queen Elizabeth Hospital
Gayton Road
King's Lynn
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PE30 4ET

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Trust Headquarters
Acre Street
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HD3 3EA

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
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Carlisle
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CA2 7HY

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
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BD9 6RJ

Study participating centre
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BS10 5NB

Study participating centre
James Paget University Hospitals NHS Foundation Trust
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NR31 6LA

Study participating centre
Southport and Ormskirk Hospital NHS Trust
Town Lane
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United Kingdom
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Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
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United Kingdom
S5 7AU

Study participating centre
Whittington Health NHS Trust
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United Kingdom
N19 5NF

Study participating centre
Somerset NHS Foundation Trust
Musgrove Park Hospital
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TA1 5DA

Sponsor information

Organisation
Wrightington, Wigan and Leigh NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.wwl.nhs.uk/

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 127739

Results and Publications

Publication and dissemination plan
Additional documentation will be added to the NIHR website when available. Exact plans unknown but planned publication as an NIHR HTA Monograph and in international, open-access peer-reviewed journals. Results will be disseminated through the local networks, and at national and international meetings in surgical care. The study findings will be presented at national and international meetings of organisations such as the British Orthopaedic Association Annual Congress, UK Orthopaedic Trauma Society, the British Shoulder and Elbow Society, North American Orthopaedic Trauma Association, European Federation of National Associations of Orthopaedics and Traumatology (EFORT), European Shoulder and Elbow Society (SECEC) and American Academy of Orthopaedic Surgeons. The findings will also be disseminated to participants in the form of a plain English summary which will be agreed by the Patient and Public Involvement (PPI) group.

Intention to publish date
30/09/2025

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. David Torgerson (David.Torgerson@york.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/01/2023	24/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1	21/02/2024	17/06/2024	No	No
Other files	Health economics analysis plan version 1	14/05/2024	19/06/2024	No	No