ISRCTN11981704 https://doi.org/10.1186/ISRCTN11981704

Surgery or using a sling to support the arm for treating adults with a broken collarbone near the shoulder joint (displaced fracture of the distal clavicle)

Submission date
24/07/2023

Recruitment status
Recruiting

Registration date
31/07/2023

Overall study status
Ongoing

Last Edited
06/06/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Fractures of the clavicle, which primarily occur in young males, constitute 2.6–5% of all fractures in adults. Distal clavicle fractures account for 20-25% of all clavicle fractures. These are treated with an operation, involving fracture fixation, or with sling immobilisation. Patients treated with surgery may have a reduced risk of the fracture not healing (non-union) and may have quicker recovery. However, they are at risk of complication; (estimated at 48%) including infection, plate breakage and refracture after metal removal. Upper limb support with a sling, typically between 2 and 4 weeks, restricts activity whilst providing comfort during the early painful stages of healing. The risk of non-union with a sling can be up to 35-40% but appears to cause minimal functional deficits in most individuals. If a non-union occurs, and surgical intervention is indicated, it can prolong the treatment period and increase costs. Using HES data for 2019 and HRG codes the cost to the NHS of surgical fixation in this fracture population is approximately £6 million per annum. At a time when the NHS is under more pressure than ever with the impact of COVID-19, it is important to answer the question of whether a potentially cheaper, safe and non-surgical option can replace more costly and invasive surgery.
The study aims to determine whether self-reported functional outcome, measured by the Disability of Arm, Shoulder and Hand (DASH) at one year, following sling immobilisation is not inferior to surgical fixation in adults with a displaced fracture of the distal clavicle and whether this is a cost-effective treatment option.

Who can participate?
The target population is adults with a radiological diagnosis of a displaced fracture of the distal clavicle that does not involve the acromioclavicular joint. The setting will be Major Trauma Centres and Trauma Units within the United Kingdom. Patients will be identified either in the Emergency Department or Fracture Clinic and will attend for routine out-patient appointment at 6 weeks, 3 and 12 months. Data will also be collected at 6 months.

What does the study involve?
If a participant decides to take part in the study they will be asked for written consent (either on paper or electronically) and to answer a list of questions. Taking part in this study means the patient or surgeon can't choose the treatment. Instead, a scientific process called randomisation determines which treatment the participant receives. This will be a 50:50 chance of wearing a sling or having surgery. To find out which treatment for broken collarbones works best, we will regularly contact all 214 patients who take part in our study. This will include attending hospital when feasible for routine appointments at 6 weeks, 3 and 12 months from taking part in the study. This will include an assessment of bone healing and whether any further treatment is necessary. Participants will also be asked to complete questionnaires electronically or on paper at 6 weeks, 3, 6 and 12 months after their decision to take part in the study.

What are the possible benefits and risks of participating?
Treating this type of collarbone injury can only be improved with the help of patients. It is hoped taking part will help improve medical care for future patients and be a rewarding experience and the patient may also have more support because of the wider team involved in this research. All surgery involves risks, such as from general anaesthesia, bleeding, deep vein thrombosis, damage to nerves and blood vessels in the surgical area and infection. Patients treated with a sling may experience swelling, bruising, discomfort or stiffness. Patients may also need surgery after initial sling care if the bone does not heal. However, there is no increased risk to a patient by taking part in the study as the NHS has treated patients in these ways with this type of collarbone injury for many years.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2022 to June 2027

Who is funding the study?
The study is funded by the National Institute for Health Research (Health Technology Assessment) programme (UK)

Who is the main contact?
ytu-didact@york.ac.uk
Stephen Brealey, stephen.brealey@york.ac.uk
Sam Swan, sam.swan@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/trials/ytutrialsandstudies/trials/didact/

Contact information

Type(s)
Principal Investigator

Contact name
Mr Harvinder Singh

ORCID ID
https://orcid.org/0000-0002-8686-2802

Contact details
University Hospitals of Leicester NHS trust
Balmoral Building
Infirmary Square
Leicester
United Kingdom
LE1 5WW
+44 (0)7739714549
Harvinder.P.Singh@uhl-tr.nhs.uk

Type(s)
Scientific

Contact name
Dr Stephen Brealey

ORCID ID
https://orcid.org/0000-0001-9749-7014

Contact details
York Trials Unit
Department of Health Sciences
University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 321357
stephen.brealey@york.ac.uk

Type(s)
Public

Contact name
Mrs Sam Swan

ORCID ID
https://orcid.org/0009-0000-2255-1012

Contact details
York Trials Unit
Department of Health Sciences
University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 328511
sam.swan@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
321203

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 321203, CPMS 56625

Study information

Scientific Title
Surgery compared with sling immobilisation in the management of adults with a displaced fracture of the distal clavicle (DIDACT): a multi-centre, pragmatic, parallel group, non-inferiority, randomised controlled trial

Acronym
DIDACT

Study objectives
The primary objective of DIDACT is to determine whether self-reported functional outcome, measured by the Disability of Arm, Shoulder and Hand (DASH) at 12 months, following sling immobilisation is not inferior to surgical fixation in adults with a displaced fracture of the distal clavicle.

Secondary objectives include confirming the feasibility of the study in a 12 month internal pilot, determining the effectiveness of the two treatment options in adults with a displaced fracture of the distal clavicle, and to determine the cost-effectiveness of the two treatments.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/07/2023, East of England - Essex Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8000; Essex.REC@hra.nhs.uk), ref: 23/EE/0123

Study design
Two-arm pragmatic multi-centre randomized non-inferiority trial with parallel groups with a 12-month internal and a full health economic evaluation

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
A radiological diagnosis of a displaced fracture of the distal clavicle that does not involve the acromioclavicular joint.

Interventions
DIDACT is a two-arm, pragmatic, multi-centre, randomised, non-inferiority trial with parallel groups, allocated on a 1:1 ratio using random permuted blocks of random block size and stratified by age (<65 or ≥65 years). There will be a 12 month internal pilot to assess the assumptions about site set up and recruitment. The trial will include a full health economic evaluation. As with many surgical trials, it will not be feasible to blind patients, surgeons, or outcome assessors to the treatment allocation.

Intervention: Surgical Fixation: Locking plate fixation, with or without coracoclavicular (CC) sling, or CC reconstruction alone.

Comparator: Sling Immobilization: upper limb support with a sling, typically for 2 to 4 weeks, followed by surgical fixation if symptomatic non-union of the fracture typically at the 3 month follow-up

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient-reported functional outcome measured by the Disability of Arm, Shoulder and Hand (DASH) at 12 months.

Secondary outcome measures
1. Patient-reported functional outcome measured by DASH score at 6 weeks, 3 and 6 months, and over 12 months
2. Shoulder pain measured using an 11-item unidimensional numerical rating scale of pain intensity in adults with 0 representing ‘no pain’ and 10 representing ‘worst imaginable pain’ in the past 24 hours at 6 weeks, 3, 6, and 12 months
3. Quality of life measured using EQ5D-5L at 6 weeks, 3, 6, and 12 months
4. Complications (e.g. infections, re-operations) measured using Centres for Disease Control (CDC) and Prevention definition for superficial and deep infection and record on a bespoke CRF rehospitalisation (e.g. repeat surgery to remove metalwork), nerve and skin problems and collected at 6 weeks, 3 and 12 months
5. Fracture healing (e.g. union, nonunion, malunion) measured using routine radiographs (typically anteroposterior and axial views) by the participating surgeons in clinic at 3 and 12 months
6. Patient preferences, satisfaction with the appearance of their shoulder/sensitivity or pain to

touch, measured using a 5-item unidimensional Likert scale that ranges from ‘Very satisfied’ to ‘Very dissatisfied’ at 12 months and range of movement measured by participants using a diagram based questionnaire at 12 months

Overall study start date
01/11/2022

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or older.
2. Displaced extra-articular (outside the joint) fracture of the distal clavicle based on routine radiographic assessment, with or without polytrauma.
3. Able and willing to give consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
214

Key exclusion criteria
1. The index injury is >21 days.
2. An upper extremity fracture both more proximal or distal to the same affected shoulder e.g. floating shoulder.
3. The fracture is open.
4. The fracture is complicated by local tumour deposits.
5. The fracture is associated with a nerve palsy or vessel injury.
6. Comorbidities precluding surgery or anaesthesia.
7. Unable or unwilling to give consent.
8. Must not be related to any member of the local study team.

Date of first enrolment
01/09/2023

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

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

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

Study participating centre
United Lincolnshire Hospitals NHS Trust
Pilgrim Hospital Boston
Sibsey Road
Boston, Lincolnshire
United Kingdom
PE21 9QS

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Huddersfield Royal Infirmary
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
Kettering General Hospital NHS Foundation Trust
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Broadgreen Hospital
Thomas Drive
Liverpool
United Kingdom
L14 3LB

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
South Tees Hospitals NHS Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Northampton
Northampton General Hospital
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre

North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

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

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Wrightington Hospital NHS Trust
Hall Lane
Wrightington
Wigan
United Kingdom
WN6 9EP

Study participating centre

Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
East Cheshire NHS Trust
Macclesfield District Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

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

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

Study participating centre

NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

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

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

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

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW
+44 (0)116 258 4109
uhlsponsor@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.leicestershospitals.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A number of dissemination channels will be used to inform clinicians, patients and the public about the project and the results of the study, including:
1. The study protocol will be published in a peer-reviewed, open access journal, before the end of recruitment.
2. A HTA monograph will be produced.
3. On completion of the study, the findings of the trial will be presented at national and international meetings of organisations that will target orthopaedic surgeons such as the British Orthopaedic Association (BOA) Annual Congress and the British Shoulder and Elbow Society (BESS).
4. The study findings and patient-focused outputs will be cascaded to trainee surgeon networks (e.g. BOTA, CORNET) and we will seek to upload these outputs on their websites. The study findings will also be cascaded to Industry who produce the implants and also to Getting It Right First Time (GIRFT) which is a national programme designed to improve medical care within NHS by reducing unwarranted variations.
5. The study report will be published in peer reviewed high impact general medical and orthopaedic journals.
6. A plain English summary leaflet of the study findings, will be produced and made available to participants, members of our user group and relevant patient-focused websites. In conjunction with the PAG we will develop an infographic and an animation to disseminate the findings.
7. The executive summary and copy of the trial report will be sent to NICE and other relevant bodies.
8. The findings of the SWAT will be disseminated in a relevant journal read by trialists and disseminated at relevant conferences.
9. These outputs will also be uploaded to various webpages (e.g. Sponsor, YTU, BESS, Wikipedia, ISRCTN registry).

The various outputs that we produce will be freely available to the NHS and public and is likely to only require IP protection with the use of a copyright statement from the Sponsor.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
All data requests should be submitted to the Chief Investigator as will be specified in our publication plan. Access to anonymised data may be granted following review with the Trial

Management Group and agreement of the Chief Investigator and Sponsor. Related documents including the statistical analyses plan will be available on request.
Harvinder.P.Singh@uhl-tr.nhs.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	23/06/2023	28/07/2023	No	Yes
Protocol file	version 1.0	12/04/2023	28/07/2023	No	No
Protocol file	version 3.0	11/11/2024	28/02/2025	No	No
Participant information sheet	version 2.1	13/01/2025	06/06/2025	No	Yes