

# 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)

<b>Submission date</b> 24/07/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/03/2026	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 January 2028

### 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

## 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**

Integrated Research Application System (IRAS)

321203

## Central Portfolio Management System (CPMS)

56625

# Study information

### Scientific Title

Sling immobilisation compared with surgery 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

### Study type(s)

Treatment

### 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

Current interventions as of 18/09/2025:

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: 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

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

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Previous 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(s)**

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

## **Key secondary outcome(s)**

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

**Completion date**

01/01/2028

## **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**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**

31/12/2026

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**

**University Hospitals of Leicester NHS Trust**

Leicester Royal Infirmary

Infirmary Square

Leicester

England

LE1 5WW

**Study participating centre**

**Barts Health NHS Trust**

The Royal London Hospital

80 Newark Street

London

England

E1 2ES

**Study participating centre**

**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

England

B15 2GW

**Study participating centre**

**United Lincolnshire Hospitals NHS Trust**

Pilgrim Hospital Boston  
Sibsey Road  
Boston, Lincolnshire  
England  
PE21 9QS

**Study participating centre**

**West Suffolk NHS Foundation Trust**

West Suffolk Hospital  
Hardwick Lane  
Bury St. Edmunds  
England  
IP33 2QZ

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Hills Road  
Cambridge  
England  
CB2 0QQ

**Study participating centre**

**Royal Devon and Exeter Hospital**

Royal Devon & Exeter Hospital  
Barrack Road  
Exeter  
England  
EX2 5DW

**Study participating centre**

**Gloucestershire Hospitals NHS Foundation Trust**

Great Western Road  
Gloucester  
England  
GL1 3NN

**Study participating centre**

**Calderdale and Huddersfield NHS Foundation Trust**

Huddersfield Royal Infirmary  
Acre Street

Lindley  
Huddersfield  
England  
HD3 3EA

**Study participating centre**  
**Kettering General Hospital NHS Foundation Trust**  
Rothwell Road  
Kettering  
England  
NN16 8UZ

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

**Study participating centre**  
**Medway NHS Foundation Trust**  
Medway Maritime Hospital  
Windmill Road  
Gillingham  
England  
ME7 5NY

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

**Study participating centre**  
**North Bristol NHS Trust**  
Southmead Hospital  
Southmead Road  
Westbury-on-trym

Bristol  
England  
BS10 5NB

**Study participating centre**  
**Oxford University Hospitals**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
England  
OX3 9DU

**Study participating centre**  
**Salisbury NHS Foundation Trust**  
Salisbury District Hospital  
Odstock Road  
Salisbury  
England  
SP2 8BJ

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

**Study participating centre**  
**Wrightington Hospital NHS Trust**  
Hall Lane  
Wrightington  
Wigan  
England  
WN6 9EP

**Study participating centre**  
**Somerset NHS Foundation Trust**  
Trust Management  
Lydeard House  
Musgrove Park Hospital

Taunton  
England  
TA1 5DA

**Study participating centre**

**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**

Nottingham University Hospital  
Derby Road  
Nottingham  
England  
NG7 2UH

**Study participating centre**

**East Cheshire NHS Trust**

Macclesfield District Hospital  
Victoria Road  
Macclesfield  
England  
SK10 3BL

**Study participating centre**

**Hull University Teaching Hospitals NHS Trust**

Hull Royal Infirmary  
Anlaby Road  
Hull  
England  
HU3 2JZ

**Study participating centre**

**Tayside**

Ninewells Hospital  
Dundee  
Scotland  
DD1 9SY

**Study participating centre**

**NHS Greater Glasgow and Clyde**

J B Russell House  
Gartnavel Royal Hospital  
1055 Great Western Road Glasgow  
Glasgow

Scotland  
G12 0XH

**Study participating centre**

**University Hospitals of Derby and Burton NHS Foundation Trust**  
Royal Derby Hospital  
Uttoxeter Road  
Derby  
England  
DE22 3NE

**Study participating centre**

**James Paget University Hospitals NHS Foundation Trust**  
Lowestoft Road  
Gorleston  
Great Yarmouth  
England  
NR31 6LA

**Study participating centre**

**North West Anglia NHS Foundation Trust**  
Peterborough City Hospital  
Bretton Gate  
Bretton  
Peterborough  
England  
PE3 9GZ

**Study participating centre**

**North Tees and Hartlepool NHS Foundation Trust**  
University Hospital of Hartlepool  
Holdforth Road  
Hartlepool  
England  
TS24 9AH

**Study participating centre**

**Hampshire Hospitals NHS Foundation Trust**  
Basingstoke and North Hampshire Hos  
Aldermaston Road  
Basingstoke

England  
RG24 9NA

**Study participating centre**  
**University Hospital Lewisham**  
Lewisham High Street  
London  
England  
SE13 6LH

**Study participating centre**  
**Northern Care Alliance NHS Foundation Trust**  
Salford Royal  
Stott Lane  
Salford  
England  
M6 8HD

**Study participating centre**  
**Aberdeen Royal Infirmary**  
Foresterhill Road  
Aberdeen  
Scotland  
AB25 2ZN

**Study participating centre**  
**Wrexham Maelor Hospital**  
Croesnewydd Road  
Wrexham Technology Park  
Wrexham  
England  
LL13 7TD

## **Sponsor information**

**Organisation**  
University Hospitals of Leicester NHS Trust

**ROR**

## 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

### 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?
<a href="#">Protocol article</a>		08/10/2025	03/03/2026	Yes	No
<a href="#">Participant information sheet</a>	version 1.1	23/06/2023	28/07/2023	No	Yes
<a href="#">Participant information sheet</a>	version 2.1	13/01/2025	06/06/2025	No	Yes
<a href="#">Participant information sheet</a>	version 3.0	04/07/2025	03/03/2026	No	Yes
<a href="#">Protocol file</a>	version 1.0	12/04/2023	28/07/2023	No	No

<a href="#">Protocol file</a>	version 3.0	11/11/2024	28/02/2025	No	No
<a href="#">Protocol file</a>	version 4.0	04/07/2025	04/03/2026	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes