

# Surgery or cast for injuries of the epicondyle in children's elbows

<b>Submission date</b> 11/03/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2019	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/01/2026	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Broken bones of the elbow are common in children. Doctors have varying opinions about the best treatment for one particular type of elbow break, called a 'medial epicondyle fracture'. Some surgeons argue that these breaks should be treated with surgery to fix the bone with wires or screws, whilst others argue that treating the bone in a cast will give just as good results, without the risks and scars associated with surgery. The research to now is of poor quality and has results supporting both arguments. This means that the treatment that children receive is dependent on the beliefs and understanding of the surgeon, rather than proper science. Perhaps unsurprisingly, half of children in the UK are treated with surgery, and half with a cast. High-quality research is urgently needed to answer this question. Children, parents and doctors all agree that how well a child can use their arm is the most important thing to find out.

### Who can participate?

Children with this injury (medial epicondyle fracture of the elbow) are usually around 10/11 years old, though anyone between 7 and 15 years can participate. It is hoped that 334 children will participate over a two year period from more than 35 hospitals. This number is calculated based on previous scientific research to ensure that the study is large enough to reach a firm conclusion.

### What does the study involve?

Participants are randomly allocated to either rest the arm in plaster cast for up to 4 weeks to allow it to heal by itself, or to undergo surgery to fix the bone, usually with a screw and a splint or cast for up to 4 weeks. Questions will be asked just after the doctors have found out the elbow is broken, and then after 6 weeks, 3, 6 and 12 months. The most important follow-up point is at 12 months, which is called the 'primary outcome'. The researchers will ask questions about pain, activities, feelings, hospital attendances, school attendance and costs incurred in relation to this injury. Parents have advised to avoid lots of paper documents, instead a website and videos/animations will be used to explain the study, and e-mails and text messages will be used to keep in touch with families. Further questions will be asked annually until the child reaches the age of 16.

What are the possible benefits and risks of participating?

Each of these routinely used treatments has potential advantages and disadvantages. Resting the arm in a plaster cast avoids surgery but healing may be slower, which may lead to an unstable elbow causing pain, stiffness and/or clunking and may rarely need more complex surgery later on. Surgery to fix the bone may lead to faster healing, but there are risks of surgery which include those associated with an anaesthetic (low risk), wound healing problems, pain or stiffness, injury to nerves supplying the fingers and breakage of the bone or metal. There is commonly the need for a second surgery to remove the screw once the bone has healed.

Where is the study run from?

The study is run from the University of Oxford, based at the John Radcliffe Hospital in Oxford, UK

When is the study starting and how long is it expected to run for?

October 2018 to December 2029

Who is funding the study?

National Institute for Health Research, Health Technology Assessment (UK)

Who is the main contact?

Mr Daniel Perry

sciencekids@ndorms.ox.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Louise Spoors

### ORCID ID

<https://orcid.org/0000-0003-0488-0087>

### Contact details

Kadoorie Centre

John Radcliffe Hospital

Oxford

United Kingdom

OX3 9DU

+44 (0)1865 228929

SCIENCEKids@ndorms.ox.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

259931

**Protocol serial number**

CPMS 41515; HTA 17/18/02, IRAS 259931

## Study information

**Scientific Title**

Surgery or Cast for Injuries of the Epicondyle in Children's Elbows (SCIENCE): a multi-centre prospective randomised superiority trial of operative fixation versus non-operative treatment for medial epicondyle fractures of the humerus in children

**Acronym**

SCIENCE

**Study objectives**

The aim of this pragmatic randomised controlled trial is to evaluate the clinical and cost-effectiveness of operative fixation versus non-operative treatment for displaced medial epicondyle fractures of the elbow in children.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 25/03/2019, North West Greater Manchester Central (3rd Floor Barlow House HRA RES Centre- Manchester M1 3DZ; +44 (0)207 104 8225; nrescommittee.northwest-gmcentral@nhs.net), ref: 19/NW/0158

**Study design**

Randomized; Interventional; Design type: Treatment, Surgery

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Medial epicondyle fractures of the humerus

**Interventions**

Current interventions as of 19/07/2019:

Randomisation:

The patient will be randomised after consent. All hospital treatment areas have access to the internet so will access the randomisation service in real time i.e. there will be no delay in patient treatment.

Consented children will be randomised to one of two intervention groups (1:1) using a computer randomisation service provided by OCTRU.

Randomisation will be performed using a minimisation algorithm including a random element to ensure balanced allocation of participants across the two treatment groups stratified by centre and dislocation status of the elbow at presentation (i.e. dislocated or not dislocated).

#### Operative fixation:

Children are admitted to hospital for surgery, which typically is scheduled on a daytime trauma operating session, though patients can be enrolled irrespective of the time of presentation/surgery. Children undergo a general anaesthetic. After the skin has been covered in antiseptic, an incision will be made over the medial epicondyle paying particular attention to the location of the ulna nerve. The bone fragments will be opposed in the optimal position achievable under direct vision. A record will be made of the type of fixation used. The bone fragments will be fixed using the preferred technique of the surgeon (i.e. screw/wire(s)). Although, the basic principles of fixation are inherent in the technique, there are several different options available to the surgeon, with the most common being screw fixation. The type of implant, size and insertion technique are not believed to affect the outcome, and will be left entirely to the discretion of the surgeon as per their normal practice. At the end of the procedure, a sling/plaster/splint/bandage will be applied as per the standard surgical practice. The elbow will be allowed to mobilise as per the usual practice of the treating surgeon under the direction of the clinical team, though fixed immobilisation in a cast should not be used for more than 4 weeks post randomisation.

#### Non-operative treatment;

This technique involves immobilisation of the elbow to rest the elbow at around 90 degrees of flexion. The immobilisation device (i.e. cast/splint/bandage etc) is not applied with the intention of directly opposing the bone fragments, and therefore the bone fragments will not align perfectly. In this pragmatic trial the duration and method of immobilisation will be left to the discretion of the treating surgeon as per their usual technique, and will be worn as per the standard practice of the treating surgeon. Subsequently, the elbow will be allowed to mobilise as pain allows under the direction of the clinical team. Fixed immobilisation in a cast should not be used for more than 4 weeks post randomisation.

#### Previous interventions:

##### Randomisation:

The patient will be randomised after consent. All hospital treatment areas have access to the internet so will access the randomisation service in real time i.e. there will be no delay in patient treatment.

Consented children will be randomised to one of two intervention groups (1:1) using a computer randomisation service provided by OCTRU. Randomisation allocation will be implemented using stratification by centre and elbow dislocation status on presentation to the emergency department with randomisation schedules prepared by the trial statistician and embedded in the online system.

#### Operative fixation;

Children are admitted to hospital for surgery, which typically is scheduled on a daytime trauma operating session, though patients can be enrolled irrespective of the time of presentation/surgery. Children undergo a general anaesthetic. After the skin has been covered in antiseptic, an incision will be made over the medial epicondyle paying particular attention to the location of the ulna nerve. The bone fragments will be opposed in the optimal position achievable under direct vision. A record will be made of the type of fixation used. The bone fragments will be fixed using the preferred technique of the surgeon (i.e. screw/wire(s)). Although, the basic principles of fixation are inherent in the technique, there are several different options available to the surgeon, with the most common being screw fixation. The type of implant, size and insertion technique are not believed to affect the outcome, and will be left entirely to the discretion of the surgeon as per their normal practice. At the end of the procedure, a sling/plaster/splint/bandage will be applied as per the standard surgical practice. The elbow will be

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### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Upper limb function measured using the Patient Reported Outcomes Measurement Information System (PROMIS) Upper Extremity Score for Children at 1 year post-randomisation

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

1. Upper limb function measured using the PROMIS Upper Extremity Score at Week 6, Months 3 and 6
2. Sports and performing arts participation measured using the DASH S/PA Module (a validated assessment of higher-level upper limb function) at Week 6, Months 3, 6 and 12
3. Pain measured using the Wong-Baker FACES Pain Rating Scale at Week 6, Months 3, 6 and 12
4. Quality of life measured using EQ5DY at Week 6, Months 3, 6 and 12
5. Complication rate, including the need for further operative fixation, at Weeks 4 and 6, Months 3, 6 and 12
6. Cost-effectiveness of the two treatments to the NHS and broader society at Months 3, 6 and 12
7. Barriers and facilitators to recruitment to this study and other paediatric surgical trials (pilot phase only) assessed using qualitative interviews with children, parent/guardians and trial staff

### **Completion date**

31/12/2029

## **Eligibility**

### **Key inclusion criteria**

1. Radiographic evidence of a displaced medial epicondyle fracture of the humerus, with fracture displacement determined by the surgeon as per their usual clinical practice
2. Aged between 7 and 15 years old inclusive

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

7 years

**Upper age limit**

15 years

**Sex**

All

**Total final enrolment**

335

**Key exclusion criteria**

1. The injury is more than two weeks old
2. There is incarceration of the medial epicondyle fragment within the elbow joint
3. The injury is part of a complex elbow fracture (i.e. fracture extending into the joint)
4. There are other fractured bones elsewhere in the body, in addition to the elbow injury
5. The elbow, if dislocated, is unable to be realigned into a satisfactory position in the emergency department.
6. There is evidence that the patient and/or parent/guardian would be unable to adhere to trial procedures or complete follow-up, such as insufficient English language comprehension, developmental delay or a developmental abnormality or no access by parents to the internet

**Date of first enrolment**

01/04/2019

**Date of final enrolment**

22/09/2023

**Locations****Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

New Zealand

**Study participating centre**  
**Royal Aberdeen Children's Hospital**

-  
Aberdeen  
Scotland  
AB25 2ZG

**Study participating centre**  
**Airedale General Hospital**

Skipton Road  
West Yorkshire

-  
England  
BD20 6TD

**Study participating centre**  
**Alder Hey Children's Hospital**

Eaton Road  
Liverpool  
England  
L12 2AP

**Study participating centre**  
**Basingstoke & North Hampshire Hospital**

-  
Basingstoke  
England  
RG24 9NA

**Study participating centre**  
**The Royal Belfast Hospital for Sick Children**

274 Grosvenor Road  
Belfast  
Northern Ireland  
BT12 6BA

**Study participating centre**  
**Birmingham Children's Hospital**

Steelhouse Ln

Birmingham  
England  
B4 6NH

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
England  
BD9 6RJ

**Study participating centre**  
**Royal Alexandra Children's Hospital**  
Eastern Road  
Brighton  
England  
BN2 5BE

**Study participating centre**  
**Bristol Royal Hospital for Children**  
Upper Maudlin St  
Bristol  
England  
BS2 8BJ

**Study participating centre**  
**University Hospital Wales**  
Heath Park Way  
Cardiff  
Wales  
CF14 4XW

**Study participating centre**  
**University Hospital Coventry**  
Clifford Bridge Rd  
Coventry  
England  
CV2 2DX

**Study participating centre**  
**Hull Royal Infirmary**  
Anlaby Rd  
Hull  
England  
HU3 2JZ

**Study participating centre**  
**Leeds General Infirmary**  
Great George St  
Leeds  
England  
LS1 3EX

**Study participating centre**  
**Leicester Royal Infirmary**  
Infirmary Square  
Leicester  
England  
LE1 5WW

**Study participating centre**  
**Luton and Dunstable Hospital**  
Lewsey Rd  
Luton  
England  
LU4 0DZ

**Study participating centre**  
**Tunbridge Wells Hospital**  
Tonbridge Rd  
Pembury  
Royal Tunbridge Wells  
England  
TN2 4QJ

**Study participating centre**  
**Royal Manchester Children's Hospital**  
Oxford Rd

Manchester  
England  
M13 9WL

**Study participating centre**  
**Milton Keynes University Hospital**  
Standing Way  
Eaglestone  
Milton Keynes  
England  
MK6 5LD

**Study participating centre**  
**Royal Victoria Infirmary**  
-  
Newcastle upon Tyne  
England  
NE1 4LP

**Study participating centre**  
**Jenny Lind Children's Hospital**  
Norfolk and Norwich University Hospital  
Colney Lane  
Norwich  
England  
NR4 7UY

**Study participating centre**  
**Nottingham University Hospital (Queen's Medical Centre)**  
Derby Rd  
Nottingham  
England  
NG7 2UH

**Study participating centre**  
**John Radcliffe Hospital**  
Headly Way  
-  
England  
OX3 9DU

**Study participating centre**  
**Derriford Hospital**  
Derriford Rd  
Plymouth  
England  
PL6 8DH

**Study participating centre**  
**Queen Alexandra Hospital**  
Southwick Hill Rd  
Hampshire  
-  
England  
PO6 3LY

**Study participating centre**  
**Royal London Hospital**  
Whitechapel  
-  
England  
E1 1BB

**Study participating centre**  
**Royal Stoke University Hospital**  
Newcastle Road  
Stoke-on-Trent  
England  
ST4 6QG

**Study participating centre**  
**Sheffield Children's Hospital**  
Western Bank  
Sheffield  
England  
S10 2TH

**Study participating centre**  
**James Cook University Hospital**  
Marton Rd

Middlesbrough  
England  
TS4 3BW

**Study participating centre**  
**University Hospital Southampton**  
Tremona Rd  
Southampton  
England  
SO16 6YD

**Study participating centre**  
**St George's Hospital**  
Blackshaw Rd  
London  
England  
SW17 0QT

**Study participating centre**  
**Arrowe Park Hospital**  
Arrowe Park Road  
Upton  
Wirral  
England  
CH49 5PE

**Study participating centre**  
**Basildon University Hospital**  
Nethermayne  
Basildon  
England  
SS16 5NL

**Study participating centre**  
**Broomfield Hospital**  
Court Rd  
Broomfield  
Chelmsford  
England  
CM1 7ET

**Study participating centre**  
**Countess of Chester Hospital**  
Liverpool Rd  
Chester  
England  
CH2 1UL

**Study participating centre**  
**Royal Cornwall Hospitals NHS Trust**  
-  
Truro  
England  
TR1 3HD

**Study participating centre**  
**Royal Derby Hospital**  
Uttoxeter Road  
Derby  
England  
DE22 3NE

**Study participating centre**  
**Epsom Hospital**  
Dorking Road  
Epsom  
England  
KT18 7EG

**Study participating centre**  
**Evelina London Children's Hospital**  
Westminster Bridge Rd  
Lambeth  
London  
England  
SE1 7EH

**Study participating centre**  
**Leighton Hospital**  
Middlewich Road

Leighton  
Crewe  
England  
CW1 4QJ

**Study participating centre**  
**Macclesfield District General Hospital**  
Victoria Road  
Macclesfield  
England  
SK10 3BL

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

**Study participating centre**  
**Northampton General Hospital**  
Cliftonville  
Northampton  
England  
NN1 5BD

**Study participating centre**  
**Pinderfields Hospital**  
Aberford Road  
Wakefield  
England  
WF1 4DG

**Study participating centre**  
**Royal Berkshire Hospital**  
London Road  
Craven Road  
Reading  
England  
RG1 5AN

**Study participating centre**  
**Royal Free Hospital**  
Pond Street  
London  
England  
NW3 2QG

**Study participating centre**  
**Salisbury District Hospital**  
-  
Salisbury  
England  
SP2 8BJ

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
England  
SR4 7TP

**Study participating centre**  
**Warrington (TBC)**  
-  
Warrington  
England  
-

**Study participating centre**  
**Wexham Park Hospital**  
Wexham Park  
Slough  
England  
SL2 4HL

**Study participating centre**  
**Whiston Hospital**  
Warrington Road  
Prescot

England  
L35 5DR

**Study participating centre**  
**Royal Hampshire County Hospital (RHCH)**  
Romsey Road  
Winchester  
England  
SO22 5DG

**Study participating centre**  
**Yeovil District Hospital**  
Higher Kingston  
Yeovil  
England  
BA21 4AT

**Study participating centre**  
**West Suffolk Hospital**  
Hardwick Ln  
Bury Saint Edmunds  
England  
IP33 2QZ

**Study participating centre**  
**Barnsley Hospital**  
Gawber Road  
Barnsley  
England  
S75 2EP

**Study participating centre**  
**Bedford Hospital**  
Kempston Rd  
Bedford  
England  
MK42 9DJ

**Study participating centre**

**Blackpool Victoria Hospital**  
Whinney Heys Road  
Blackpool  
England  
FY3 8NR

**Study participating centre**  
**Addenbrooke's Hospital**  
Hills Road  
Cambridge  
England  
CB2 0QQ

**Study participating centre**  
**Doncaster Royal Infirmary**  
Armthorpe Road  
Doncaster  
England  
DN2 5LT

**Study participating centre**  
**Frimley Park Hospital**  
Portsmouth Road  
Frimley  
Camberley  
England  
GU16 7UJ

**Study participating centre**  
**James Paget University Hospital**  
Lowestoft Road  
Gorleston-on-Sea  
Great Yarmouth  
England  
NR31 6LA

**Study participating centre**  
**Kettering General Hospital**  
Rothwell Road

Kettering  
England  
NN16 8UZ

**Study participating centre**  
**Musgrove Park Hospital**

-  
Taunton  
England  
TA1 5DA

**Study participating centre**  
**Ormskirk District General Hospital**

Wigan Road  
Ormskirk  
England  
L39 2AZ

**Study participating centre**  
**Peterborough City Hospital**

-  
Peterborough  
England  
PE3 9GZ

**Study participating centre**  
**Queen Margaret Hospital (Fife)**

Whitefield Road  
Dunfermline  
Scotland  
KY12 0SU

**Study participating centre**  
**Kings Mill Hospital**

Mansfield Road  
Sutton In Ashfield  
England  
NG17 4JL

**Study participating centre**

**Southend Hospital**

Prittlewell Chase  
Southend-on-Sea  
England  
SS0 0RY

**Study participating centre**

**South Tyneside District Hospital**

Harton Lane  
South Shields  
England  
NE34 0PL

**Study participating centre**

**Princess Alexandra Hospital**

Hamstel Road  
Harlow  
England  
CM20 1QX

**Study participating centre**

**Royal Devon and Exeter Hospital**

Barrack Rd  
Exeter  
England  
EX2 5DW

**Study participating centre**

**Torbay Hospital**

Torbay and South Devon NHS Foundation Trust  
Newton Rd  
Torquay  
England  
TQ2 7AA

**Study participating centre**

**Starship Children's Hospital**

2 Park Road  
Grafton  
Auckland

New Zealand  
1023

**Study participating centre**  
**The Royal Children's Hospital Melbourne**  
50 Flemington Road  
Parkville  
Australia  
3052

**Study participating centre**  
**The Children's Hospital at Westmead**  
Cnr Hawkesbury Rd & Hainsworth St  
Westmead  
Australia  
2145

**Study participating centre**  
**Children's Health Queensland Hospital and Health Service**  
501 Raymond Terrace  
South Brisbane  
Australia  
4101

## **Sponsor information**

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator (Daniel.perry@ndorms.ox.ac.uk). Applications will be considered by the Oxford Trauma and Emergency Care senior management group, with the intention to release anonymised data to academic groups for the purpose of high-quality individual patient data meta-analyses.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		20/01/2026	29/01/2026	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other files</a>	Health economics analysis plan version 1.0	20/08/2024	09/01/2025	No	No
<a href="#">Protocol file</a>	version V4.0	10/03/2021	07/04/2021	No	No
<a href="#">Protocol file</a>	version v5.0	07/06/2021	27/07/2021	No	No
<a href="#">Protocol file</a>	version 6.0	19/08/2021	23/08/2021	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	31/10/2024	09/01/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes