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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered[X] Protocol	
11/03/2019			
Registration date	Overall study status	[X] Statistical analysis plan	
18/03/2019	Ongoing	Results	
Last Edited	Condition category	Individual participant data	
09/01/2025	Injury, Occupational Diseases, Poisoning	[X] Record updated in last year	

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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

259931

ClinicalTrials.gov (NCT)

Nil known

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 costeffectiveness 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.

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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
- 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

Αll

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

Study participating centre
Royal Aberdeen Children's Hospital
Aberdeen
United Kingdom
AB25 2ZG

Study participating centre Airedale General Hospital Skipton Road West Yorkshire United Kingdom BD20 6TD

Study participating centre Alder Hey Children's Hospital Eaton Road Liverpool United Kingdom L12 2AP

Study participating centre
Basingstoke & North Hampshire Hospital
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
The Royal Belfast Hospital for Sick Children
274 Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
Birmingham Children's Hospital
Steelhouse Ln
Birmingham

United Kingdom B4 6NH

Study participating centre Bradford Royal Infirmary

Duckworth Lane Bradford United Kingdom BD9 6RJ

Study participating centre Royal Alexandra Children's Hospital

Eastern Road Brighton United Kingdom BN2 5BE

Study participating centre Bristol Royal Hospital for Children

Upper Maudlin St Bristol United Kingdom BS2 8BJ

Study participating centre University Hospital Wales

Heath Park Way Cardiff United Kingdom CF14 4XW

Study participating centre University Hospital Coventry

Clifford Bridge Rd Coventry United Kingdom CV2 2DX

Study participating centre

Hull Royal Infirmary

Anlaby Rd Hull United Kingdom HU3 2JZ

Study participating centre Leeds General Infirmary

Great George St Leeds United Kingdom LS1 3EX

Study participating centre Leicester Royal Infirmary

Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre Luton and Dunstable Hospital

Lewsey Rd Luton United Kingdom LU4 0DZ

Study participating centre Tunbridge Wells Hospital

Tonbridge Rd Pembury Royal Tunbridge Wells United Kingdom TN2 4QJ

Study participating centre Royal Manchester Children's Hospital

Oxford Rd Manchester United Kingdom M13 9WL

Study participating centre Milton Keynes University Hospital

Standing Way Eaglestone Milton Keynes United Kingdom MK6 5LD

Study participating centre Royal Victoria Infirmary

Newcastle upon Tyne United Kingdom NE1 4LP

Study participating centre Jenny Lind Children's Hospital

Norfolk and Norwich University Hospital Colney Lane Norwich United Kingdom NR4 7UY

Study participating centre Nottingham University Hospital (Queen's Medical Centre)

Derby Rd Nottingham United Kingdom NG7 2UH

Study participating centre John Radcliffe Hospital Headly Way

Headly Way United Kingdom OX3 9DU

Study participating centre Derriford Hospital Derriford Rd

Plymouth United Kingdom PL6 8DH

Study participating centre Queen Alexandra Hospital

Southwick Hill Rd Hampshire United Kingdom PO6 3LY

Study participating centre Royal London Hospital

Whitechapel United Kingdom E1 1BB

Study participating centre Royal Stoke University Hospital

Newcastle Road Stoke-on-Trent United Kingdom ST4 6QG

Study participating centre Sheffield Children's Hospital

Western Bank Sheffield United Kingdom S10 2TH

Study participating centre James Cook University Hospital

Marton Rd Middlesbrough United Kingdom TS4 3BW

Study participating centre

University Hospital Southampton

Tremona Rd Southampton United Kingdom SO16 6YD

Study participating centre St George's Hospital

Blackshaw Rd London United Kingdom SW17 0QT

Study participating centre Arrowe Park Hospital

Arrowe Park Road Upton Wirral United Kingdom CH49 5PE

Study participating centre Basildon University Hospital

Nethermayne Basildon United Kingdom SS16 5NL

Study participating centre Broomfield Hospital

Court Rd Broomfield Chelmsford United Kingdom CM1 7ET

Study participating centre Countess of Chester Hospital

Liverpool Rd

Chester United Kingdom CH2 1UL

Study participating centre Royal Cornwall Hospitals NHS Trust

Truro United Kingdom TR1 3HD

Study participating centre Royal Derby Hospital

Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre Epsom Hospital

Dorking Road Epsom United Kingdom KT18 7EG

Study participating centre Evelina London Children's Hospital

Westminster Bridge Rd Lambeth London United Kingdom SE1 7EH

Study participating centre Leighton Hospital

Middlewich Road Leighton Crewe United Kingdom CW1 4QJ

Study participating centre Macclesfield District General Hospital

Victoria Road Macclesfield United Kingdom SK10 3BL

Study participating centre Medway Maritime Hospital

Windmill Road Gillingham United Kingdom ME7 5NY

Study participating centre Northampton General Hospital

Cliftonville Northampton United Kingdom NN1 5BD

Study participating centre Pinderfields Hospital

Aberford Road Wakefield United Kingdom WF1 4DG

Study participating centre Royal Berkshire Hospital

London Road Craven Road Reading United Kingdom RG1 5AN

Study participating centre Royal Free Hospital

Pond Street London United Kingdom NW3 2QG

Study participating centre Salisbury District Hospital

Salisbury United Kingdom SP2 8BJ

Study participating centre Sunderland Royal Hospital

Kayll Road Sunderland United Kingdom SR4 7TP

Study participating centre Warrington (TBC)

Warrington United Kingdom

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Study participating centre Wexham Park Hospital

Wexham Park Slough United Kingdom SL2 4HL

Study participating centre Whiston Hospital

Warrington Road Prescot United Kingdom L35 5DR

Study participating centre Royal Hampshire County Hospital (RHCH)

Romsey Road

Winchester United Kingdom SO22 5DG

Study participating centre Yeovil District Hospital

Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre West Suffolk Hospital

Hardwick Ln Bury Saint Edmunds United Kingdom IP33 2QZ

Study participating centre Barnsley Hospital

Gawber Road Barnsley United Kingdom S75 2EP

Study participating centre Bedford Hospital

Kempston Rd Bedford United Kingdom MK42 9DJ

Study participating centre Blackpool Victoria Hospital

Whinney Heys Road Blackpool United Kingdom FY3 8NR

Study participating centre Addenbrooke's Hospital

Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre Doncaster Royal Infirmary

Armthorpe Road Doncaster United Kingdom DN2 5LT

Study participating centre Frimley Park Hospital

Portsmouth Road Frimley Camberley United Kingdom GU16 7UJ

Study participating centre James Paget University Hospital

Lowestoft Road Gorleston-on-Sea Great Yarmouth United Kingdom NR31 6LA

Study participating centre Kettering General Hospital

Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre

Musgrove Park Hospital

Taunton United Kingdom TA1 5DA

Study participating centre Ormskirk District General Hospital

Wigan Road Ormskirk United Kingdom L39 2AZ

Study participating centre Peterborough City Hospital

Peterborough United Kingdom PE3 9GZ

Study participating centre Queen Margaret Hospital (Fife)

Whitefield Road Dunfermline United Kingdom KY12 0SU

Study participating centre Kings Mill Hospital

Mansfield Road Sutton In Ashfield United Kingdom NG17 4JL

Study participating centre Southend Hospital

Prittlewell Chase Southend-on-Sea United Kingdom SSO ORY

Study participating centre South Tyneside District Hospital

Harton Lane South Shields United Kingdom NE34 0PL

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

Study participating centre Princess Alexandra Hospital

Hamstel Road

Harlow United Kingdom CM20 1QX

Study participating centre Royal Devon and Exeter Hospital

Barrack Rd Exeter United Kingdom EX2 5DW

Study participating centre Torbay Hospital

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

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 HRA research summary	Details	Date created	Date added Peer reviewed? 28/06/2023 No	Patient-facing? No
Other files	Health economics analysis plan version 1.0		09/01/2025 No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes
<u>Protocol file</u>	version V4.0	10/03/2021	07/04/2021 No	No
<u>Protocol file</u>	version v5.0	07/06/2021	27/07/2021 No	No
<u>Protocol file</u>	version 6.0	19/08/2021	23/08/2021 No	No
Statistical Analysis Plan	version 1.0	31/10/2024	09/01/2025 No	No
Study website	Study website	11/11/2025	11/11/2025 No	Yes