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

Submission date
11/03/2019

Recruitment status
No longer recruiting

Registration date
18/03/2019

Overall study status
Ongoing

Last Edited
09/01/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[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

Study website
http://www.sciencestudy.org

Contact information

Type(s)
Scientific

Contact name
Mrs Louise Spoors

ORCID ID
http://orcid.org/0000-0003-0488-0087

Contact details
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OX3 9DU
+44 (0)1865 228929
SCIENCEKids@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
259931

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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 patient information sheet

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 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.

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Intervention Type
Procedure/Surgery

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

Secondary outcome measures
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

Overall study start date
01/10/2018

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

Age group
Child

Lower age limit
7 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
UK Sample Size: 300, Overseas: 34

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
Australia

England

New Zealand

Northern Ireland

Scotland

United Kingdom

Wales

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
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
-

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
SS0 0RY

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

Sponsor details
Joint Research Office
1st floor
Boundary Brook House
Churchill Drive
Headington
England

United Kingdom
OX3 7GB

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be available prior to the completion of recruitment. The Statistical Analysis Plan and Health Economics Analysis Plan will be prepared before the final data has been collected. It is planned that each of these will be published in open-access journals.

Planned publication of the results will be via high-impact peer reviewed journals, and will be disseminated on social media using infographics and cartoons around one year after the trial has ended (2023).

Intention to publish date
30/09/2025

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?
Protocol file	version V4.0	10/03/2021	07/04/2021	No	No
Protocol file	version v5.0	07/06/2021	27/07/2021	No	No
Protocol file	version 6.0	19/08/2021	23/08/2021	No	No
HRA research summary			28/06/2023	No	No
Other files	Health economics analysis plan version 1.0	20/08/2024	09/01/2025	No	No
Statistical Analysis Plan	version 1.0	31/10/2024	09/01/2025	No	No