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Multi-centre study of children with suspected bone and/or joint infection (BJI)

Submission date 28/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/05/2023	**Overall study status** Completed	
Last Edited 03/09/2025	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
When a child is brought to the emergency department with a painful limb without an obvious injury, the most important things for doctors to consider is:
• A serious infection of their bones or joints OR
• A temporary swelling within their joints.
Serious infections in bones are rare, but can be limb and life threatening. They require urgent treatment (antibiotics) and sometimes surgery. Temporary joint swelling however, is common and resolves without any intervention within a few days. The challenge is to quickly identify which child has an infection and which has joint swelling. Telling these apart is often not easy and involves x-rays and blood tests. Often, special tests are also used, which are ultrasound and /or MRI (Magnetic Resonance Imaging) scans. Doctors around the world are unsure about the best choice of test, particularly the 'special tests', and what order tests should be performed when a bone infection is suspected.
A clear pathway outlining which tests to perform and when they are needed would help to ensure that bone infections are not missed. This would also reduce unnecessary tests on children who do not have an infection.
Aims:
1. To understand how helpful special tests (i.e. ultrasound and MRI scans) are in diagnosing bone and joint infections in children.
2. To create a pathway that doctors and nurses can use in emergency departments to more successfully diagnose bone and joint infections.
Design:
The study is a multi-centre cohort study of children with suspected OM combining a retrospective cohort and a prospective validation cohort. Similar selection criteria and data collection will be employed in both cohorts.
The study will consist of two phases:
1. A multi-centre retrospective cohort study to establish the diagnostic accuracy of MRI and USS and to develop a clinical algorithm for diagnosis;
2. A multi-centre prospective cohort study to externally validate the clinical algorithm.
3. In parallel, a qualitative study will inform the management of patients being investigated for OM, including how best to address their information needs and how to support them during the process.

Who can participate?
Prospective and Retrospective Studies:
Children and young people under 16 years old with a diagnosis of bone/joint infection (BJI) suspected by the treating clinician.
Qualitative Information Study:
Patients and families with a proven BJI and a sub-set of patients and families who have undergone investigations for suspected BJI but received other diagnoses. Also, health professionals involved with the care of children with a suspected BJI.

What does the study involve?
It is an observational study and does not involve any extra test or visits to the hospital. The research team will collect the results of all investigations children with suspected infection undergo during initial presentation and at three months (i.e. what assessments they have received, the results of these assessments and the diagnosis the child was given).
With their consent, we will contact the parents/carers of the participants at 3 months from initial presentation. This will involve a short phone call/email to find out how the child is doing and whether they received treatment anywhere else. If the child received treatment elsewhere, the research team will inform the original recruiting site and request they seek further information from the relevant non-participating hospital/GP.
The parents/carers and the child may also be invited to take part in our sub study (the qualitative information study discussed above) exploring the experiences of the clinical investigations the child receives.

What are the possible benefits and risks of participating?
There is no direct benefit from taking part in this study. However, participation will help improve the way children with a painful limb are investigated, which may lead to better care and outcomes for children in the same situation in the future. There is no risk arising from participation in the study as it is only an observational study. Participation in the study will not influence clinical decisions and treatment pathways.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
April 2022 to September 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific, Principal investigator

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318114

Protocol serial number
IRAS 318114, CPMS 55083

Study information

Scientific Title

Imaging in Paediatric Osteomyelitis (the PICBONE study): a multi-centre cohort study to understand the role of MRI and Ultrasound in the diagnosis of acute haematogenous osteomyelitis in children.

Acronym
PIC Bone

Study objectives
When a child is brought to the emergency department with a painful limb without an obvious injury, doctors are typically faced with a dilemma between two diagnoses:
• A serious, though relatively uncommon, infection of their bones or joints OR
• A non-serious, though common, temporary swelling to their joints
Serious infections in bones are rare, but can be limb and life threatening. They require urgent treatment (antibiotics) and sometimes surgery. Temporary joint swelling however, is common and resolves without any intervention within a few days. The challenge is to quickly identify which child has an infection and which has joint swelling. Telling these apart is often not easy and involves x-rays and blood tests. Often, 'special tests' are also used, which are ultrasound and /or MRI (magnetic resonance imaging) scans. Doctors around the world are unsure about the best choice of test, particularly the 'special tests', and in what order tests should be performed when a bone infection is suspected.
A clear pathway outlining which tests to perform, and when they are needed, would help to ensure that bone infections are not missed. This would also reduce unnecessary tests on children who do not have an infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/03/2023, Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 207 104 8269; solihull.rec@hra.nhs.uk), ref: 23/WM/0027

Study design
Multicentre retrospective cohort, a prospective validation cohort and a qualitative evaluation study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis of osteomyelitis (Bone/joint infection) in children aged 0-15 years

Interventions
1. Learn from children who have previously been suspected to have bone and joint infection. We will look at past records from at least 30 hospitals in the UK. These will tell us which tests were performed and when. We will work-out how useful the 'special tests' were at detecting bone infections and identify patterns in how and when tests should be performed. We will use the information to develop a pathway to investigate suspected bone infections.

2. Apply what we've learnt to diagnose future infections in children.
We will test how well the pathway that we develop works on data collected from a new group of children with suspected infections.
3. Determine the acceptability and concerns in treating bone and joint infection.
We will interview families to see if this pathway is acceptable to children, parents and doctors and assess how best to address children's and parents' needs and concerns.

Intervention Type
Other

Primary outcome(s)
Presence or absence of proven BJI, which includes osteomyelitis and/or septic arthritis measured using patient records measured at a single time point

Key secondary outcome(s))
Experience through semi-structured qualitative interviews with children and parents and focus groups with health professionals measured at a single time point

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/07/2024:

1. The child is aged between 0-15 years.
2. BJI is part of the differential diagnosis, even remotely, and even if the treating clinician believes BJI can be ruled out on the basis of the history and examination alone.
3. The duration of symptoms is less than 2 weeks at the time of attendance to acute healthcare.
4. Symptoms affecting the appendicular skeleton only.

Previous inclusion criteria:

1. The child is aged between 0-15 years.
2. The treating clinician is suspicious of a diagnosis of bone and/or joint infection.
3. The duration of symptoms is less than 2 weeks at the time of attendance to acute healthcare.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit

0 years

Upper age limit
15 years

Sex
All

Total final enrolment
7525

Key exclusion criteria
Current exclusion criteria as of 12/07/2024:

1. There is evidence that the patient and/or parent/guardian would be unable to adhere to study procedures or complete follow-up, such as developmental delay or a developmental abnormality.
2. Limited comprehension by the parent guardian of the English language. This will be assessed by the recruiting team at participating sites.
3. Suspected infections affecting the axial skeleton (skull spine, or ribs).
4. Traumatic aetiology of symptoms

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Previous exclusion criteria:

1. There is evidence that the patient and/or parent/guardian would be unable to adhere to study procedures or complete follow-up, such as developmental delay or a developmental abnormality.
2. Limited comprehension by the parent guardian of the English language. This will be assessed by the recruiting team at participating sites.

Date of first enrolment
16/06/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

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

Study participating centre
St Georges University Hospital NHS Foundation Trust
St. Georges Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Colchester Dist General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre

Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

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

Study participating centre
West Hertfordshire Teaching Hospitals NHS Trust
Trust Offices
Watford General Hospital
Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Sheffield Childrens Hospital NHS Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital

Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

Study participating centre
Airedale NHS Trust
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

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

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road

Uxbridge
United Kingdom
UB8 3NN

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

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

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester

United Kingdom
M13 9WL

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

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

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

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

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing

United Kingdom
BN11 2DH

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

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

Study participating centre
Ipswich Hospital
Heath Road

Ipswich
United Kingdom
IP4 5PD

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 current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/06/2025	10/06/2025	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	21/12/2022	03/04/2023	No	No
Protocol file	version 2.0	06/02/2024	12/07/2024	No	No
Protocol file	version 3.0	31/10/2024	19/03/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes