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

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

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? tim.theologis@msd.ox.ac.uk picbone@ndorms.ox.ac.uk

Contact information

Type(s)

Scientific, Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

318114

ClinicalTrials.gov (NCT)

Nil known

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



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

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

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

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?
<u>Protocol article</u>		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
<u>Protocol file</u>	version 1.0	21/12/2022	03/04/2023	No	No
<u>Protocol file</u>	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