

# Using procalcitonin to guide duration of antibiotics - further evaluation of the effectiveness

<b>Submission date</b> 14/09/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/12/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2026	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the BATCH trial (<https://www.isrctn.com/ISRCTN11369832>), researchers are looking at a blood marker for a bacterial infection called procalcitonin to see if it can help to identify how children and young people are responding to antibiotics that are being used to treat the infection. In this study, the researchers would like to see if two other blood markers MR-Pro-adrenomedullin (MR-proADM) and ImmunoXpert can also help provide information that will help treat children and young people with bacterial infection in the future.

### Who can participate?

Participants recruited into the BATCH trial

### What does the study involve?

The researchers would like to collect additional samples of a small amount of blood (0.5-1 ml) from the children and young people recruited into the BATCH trial. They will try to take these samples at the same time as routine blood tests are being taken, or use the leftover blood that is normally discarded by the laboratory after the routine tests are done. However, they may need to take an additional blood test at separate time points if routine bloods are not due to be collected or there is not enough routine blood leftover. The researchers will always ask permission first and will use the method of collection that participants prefer, such as finger prick, vein or arterial line (if this is already in place).

### What are the possible benefits and risks of participating?

Participants will be helping to provide information that will help treat children and young people with bacterial infections in the future. They will be given a £20 high street shopping voucher for the inconvenience of participating in the study, which is unconditional and not dependent on giving permission for any additional samples to be taken.

### Where is the study run from?

The study is led by the University of Liverpool and managed by the Centre for Trials Research at Cardiff University (UK)

When is the study starting and how long is it expected to run for?  
September 2020 to August 2024

Who is funding the study?  
National Institute for Health Research Efficacy and Mechanism Evaluation (NIHR EME)  
Programme (UK)

Who is the main contact?  
Dr Cherry-Ann Waldron  
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## Contact information

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Public

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# Additional identifiers

**Integrated Research Application System (IRAS)**  
235042

**Central Portfolio Management System (CPMS)**  
47548

**Protocol serial number**  
UoL001333

## Study information

### Scientific Title

MR-PRo-adrenomedullin (MR-proADM) and ImmunoXpert Evaluation of procalcitonin-guided antibiotic duration in Children with Infection for Stratification of Effectiveness (PRECISE)

### Acronym

PRECISE

### Study objectives

The aim of the PRECISE study is to determine if there are specific sub-groups of patients for whom a PCT-guided antibiotic algorithm may be beneficial, harmful or ineffective. It aims to identify endotypes or sub-phenotypes of infection to facilitate optimisation of antibiotic dosing and duration (when, by how much and for how long). The embedded mechanistic study within an existing RCT allows the theranostic exploration of two commercially available biomarker assays to guide judicious antibiotic use.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 13/04/2018, North West Liverpool East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048199; liverpoolcentral.rec@hra.nhs.uk), REC ref: 18/NW/0100

### Study design

Embedded mechanism of action study within the BATCH trial (ISRCTN11369832) (a multi-centre, prospective, individually randomised, open-label two-arm randomized controlled trial comparing a PCT-guided antibiotic algorithm versus usual care)

### Primary study design

Observational

### Study type(s)

Diagnostic

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

Bacterial infection

## **Interventions**

MR-proADM and ImmunoXpert analysis of blood samples of children recruited to the BATCH trial (ISRCTN11369832) who have been hospitalised with suspected or confirmed bacterial infection, randomised to the intervention arm (e.g. procalcitonin test results that feed into an algorithm that guides antimicrobial prescribing conditions) or the control arm (usual care, no PCT test).

## **Intervention Type**

Other

## **Primary outcome(s)**

Collected from patient notes up to and including day 28, or until discharge:

1. Time until IV antibiotic therapy is stopped
2. MR-proADM and ImmunoXpert scores at baseline will define subgroups for the primary comparison, and serial measurements for additional analyses

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

Collected from patient notes up to and including day 28, or until discharge:

1. Total duration of antibiotics (oral and IV)
2. Time to switch from broad-spectrum to narrow-spectrum antibiotics
3. Time to discharge from hospital
4. Suspected adverse drug reactions measured using the Liverpool Causality Assessment tool
5. Hospital-acquired infection up to Day 28

## **Completion date**

01/08/2024

# **Eligibility**

## **Key inclusion criteria**

Same as the BATCH trial (ISRCTN11369832)

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Child

## **Sex**

All

## **Total final enrolment**

407

## **Key exclusion criteria**

Same as the BATCH trial (ISRCTN11369832)

**Date of first enrolment**

01/02/2021

**Date of final enrolment**

11/10/2022

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

United Kingdom

England

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

Alder Hey Children's NHS Foundation Trust

Eaton Road

Liverpool

England

L12 2AP

**Study participating centre****Bristol Royal Hospital for Children**

University Hospitals Bristol NHS Foundation Trust

24 Upper Maudlin Street

Bristol

England

BS2 8BJ

**Study participating centre****Southampton Children's Hospital, University Hospital Southampton**

University Hospital Southampton NHS Foundation Trust

Tremona Road

Southampton

England

SO16 6YD

**Study participating centre****Children's Hospital, John Radcliffe Hospital**

Oxford University Hospitals NHS Foundation Trust

Oxford

England

OX3 9DU

# Sponsor information

## Organisation

University of Liverpool

## ROR

<https://ror.org/04xs57h96>

# Funder(s)

## Funder type

Government

## Funder Name

Efficacy and Mechanism Evaluation Programme

## Alternative Name(s)

NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Current Individual participant data (IPD) sharing statement as of 09/02/2023:

The datasets generated during the current study are available upon request from the Centre for Trials Research, Cardiff University by contacting the trial manager at [BATCH@cardiff.ac.uk](mailto:BATCH@cardiff.ac.uk). Pseudo-anonymised data will be provided upon production of the requestor's study protocol and agreement by Centre of Trials Research and study sponsor (University of Liverpool).

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## Previous Individual participant data (IPD) sharing statement:

The datasets generated during and/or analysed during the current study will be available upon request from [opendata@cardiff.ac.uk](mailto:opendata@cardiff.ac.uk) at the end of the study. The aim is to make the research data available wherever possible, subject to regulatory approvals, any terms and conditions from external providers, patient confidentiality and all laws concerning the protection of personal information. Data is generally freely available, but recipients are expected to acknowledge the original creators in any public use of the data or in publishing research results based wholly or in part upon the data – anyone requesting access to data will be asked to agree to the terms of the Creative Commons Attribution 4.0 license. The trialists may ask the requestor to cover reasonable cost for preparing and providing the data (for example physical storage and postage, where dataset size makes it impractical to provide data by electronic means).

## 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>		01/03/2026	26/03/2026	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>		30/05/2023	31/05/2023	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes