ISRCTN14945050 https://doi.org/10.1186/ISRCTN14945050

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

Submission date
14/09/2020

Recruitment status
No longer recruiting

Registration date
17/12/2020

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
235042

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 47548, IRAS 235042, 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
United Kingdom
L12 2AP

Study participating centre
Bristol Royal Hospital for Children
University Hospitals Bristol NHS Foundation Trust
24 Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Southampton Children's Hospital, University Hospital Southampton
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Children’s Hospital, John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust

Oxford
United Kingdom
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. 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).

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 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?
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	SAP article	30/05/2023	31/05/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes