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Better outcomes in babies with bacterial meningitis

Submission date
22/04/2026

Recruitment status
Recruiting

Registration date
06/07/2026

Overall study status
Ongoing

Last Edited
05/10/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Meningitis is an infection around the brain and spinal cord. In babies under 3 months, even with antibiotics around 1 in 20 die and 1 in 3 survivors have lifelong disabilities. In older children, steroids given with antibiotics reduce some harm, but it is not known whether this also helps young babies. The aim of this study is to determine whether giving dexamethasone to babies with suspected or confirmed bacterial meningitis improves survival and reduces long-term problems.

Who can participate?
Babies up to 3 months of age who doctors think have bacterial meningitis.

What does the study involve?
Babies will be randomly allocated to receive dexamethasone or standard care shortly after starting antibiotics. Because bacterial meningitis is an emergency, babies may be enrolled into the trial before parents are approached, using a deferred consent model. Parents will usually be approached within 48 hours, provided with information about the study, and asked for consent for their baby's ongoing participation and follow-up until 2 years of age.
Parents may withdraw their baby at any time without affecting their care. If a baby is later found not to have bacterial meningitis, study treatment will be stopped.
Parents will be asked to complete questionnaires at hospital discharge and at 12 and 24 months. Information from medical records will also be collected. Outcomes include survival and developmental difficulties such as deafness, reduced vision, seizures, cerebral palsy and learning problems.

What are the possible benefits and risks of participating?
The trial addresses uncertainty about whether dexamethasone improves survival and long-term outcomes in babies with bacterial meningitis and may help improve future treatment.
As bacterial meningitis is an emergency, treatment must start quickly. Based on advice from parents with experience of bacterial meningitis in their baby, the trial uses deferred consent so that treatment is not delayed and parents are not overburdened during a critical situation. Parents are approached as soon as clinically appropriate by trained staff, usually within 48 hours, to discuss the study and provide written informed consent for ongoing participation.

Dexamethasone is commonly used in babies for inflammatory conditions and is recommended for older children with meningitis, although like all medicines it can cause side effects. Potential short-term risks include raised blood glucose and, rarely, gastrointestinal bleeding. Babies will be closely monitored throughout their care.
To minimise risks, very preterm babies (<34 weeks) are excluded from receiving dexamethasone during the first week of life, treatment is stopped if bacterial meningitis becomes unlikely, and all serious events are reviewed by the trial team and an independent data monitoring committee. Parents and charities helped design the study and continue to advise on the trial.

Where is the study run from?
The National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) at the University of Oxford, England, UK, in partnership with City St George's, University of London, sponsor for the UK sites, and the University of British Columbia, sponsor for the Canadian sites, are coordinating and managing the study.

When is the study starting and how long is it expected to run for?
The total planned trial period is 1 September 2025 to 31 August 2033, with recruitment planned from 1 June 2026 to 30 November 2030

Who is funding the study?
Health Technology Assessment Programme (UK) and Canadian Institutes of Health Research (Canada)

Who is the main contact?
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Contact information

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1013356

Study information

Scientific Title
Better Outcomes in Babies with Bacterial meningitis (BOBBi) – a multisite, open-label, two-arm, parallel-group, pragmatic, randomised controlled trial to compare dexamethasone versus no dexamethasone as treatment in babies with suspected or confirmed bacterial meningitis

Acronym
BOBBi

Study objectives
The aim of the trial is to find out whether giving a short course of steroids (dexamethasone) alongside usual antibiotic treatment helps more babies from 32+0 corrected gestational weeks up to and including 3 months' corrected age (babies born at term (37+0 or greater) may be randomised until 3 months from their birth date) with suspected or confirmed bacterial meningitis survive without long-term difficulties. We will also look at how these babies are developing as they grow, to see if steroids have any longer-term effects.

1. How the babies are developing at 2 years of age (for example, movement, hearing, vision and learning)
2. The child's and family's quality of life
3. Any side effects of the steroids and how often babies need to come back to hospital or see other services
(In England, newborn hearing screen results may be obtained via the newborn screening programme [NHSP])

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/07/2026, South Central – Oxford A Research Ethics Committee (Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; oxforda.rec@hra.nhs.uk), ref: 26/SC/0146

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Open (masking not used)

Control
Active

Assignment
Single

Purpose
Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied
Bacterial meningitis (BM)

Interventions
Babies will be randomised 1:1 using a centralised randomisation system.

Intervention arm: Dexamethasone 0.15 mg/kg administered intravenously every 6 hours (total daily dose 0.6 mg/kg) for 4 days (16 doses), given alongside treatment-as-usual based on national clinical guidelines. Dexamethasone is started within 12 hours of the first antibiotic dose for suspected or confirmed bacterial meningitis and will be stopped if a virus is identified as the sole cause of meningitis, or if antibiotics are stopped.

Comparator arm: Treatment-as-usual based on national clinical guidelines without dexamethasone.

All babies will receive standard antibiotic therapy and supportive care. Follow-up includes in-hospital outcomes and parent-completed questionnaires at 12 and 24 months of age.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dexamethasone

Primary outcome(s)
Survival without moderate or severe neurodevelopmental impairment at 24 months of age corrected for prematurity in preterm babies, and 24 months actual age in term babies, assessed using parent-completed questionnaires with additional review of routine clinical follow-up information by a blinded endpoint review committee.

Key secondary outcome(s)
1. Total number of days spent in critical care - number of days of neonatal intensive care (defined as per national standards, indicated in the Country-specific Annex), number of days of paediatric intensive care (defined as per national standards, indicated in the Country-specific Annex (timepoint: between randomisation and hospital discharge (with an upper limit of 8

weeks from randomisation))
2. Length of hospital stay in days (timepoint: between randomisation and hospital discharge (with an upper limit of 8 weeks from randomisation))
3. Total number of days of antibiotic treatment for this episode of meningitis (including treatment for any relapse if applicable) (timepoint:from randomisation to termination of antibiotic treatment for meningitis (with an upper limit of 8 weeks from randomisation))
4. Relapse of suspected or confirmed bacterial meningitis (*relapse defined as the reappearance of clinical and/or laboratory features of bacterial meningitis (as described in Section 10.1: Inclusion criteria) within 2 weeks of completing treatment for this episode (timepoint: from randomisation to termination of antibiotic treatment for meningitis (with an upper limit of 8 weeks from randomisation))
5. Gastrointestinal haemorrhage (timepoint: between randomisation and hospital discharge or leading to re admission to hospital up to 8 weeks from randomisation)
6. Hypertension requiring drug treatment (timepoint: between randomisation and hospital discharge or leading to re-admission to hospital up to 8 weeks from randomisation)
7. Hyperglycaemia receiving insulin treatment (timepoint: between randomisation and hospital discharge or leading to re-admission to hospital up to 8 weeks from randomisation)
8. Invasive infection defined as isolation of a relevant bacterial or fungal organism from a normally sterile body fluid, such as pleural fluid, pericardial fluid, joint fluid, bone aspirate or deep tissue abscess (NOT from urine or CSF or blood) OR no isolation of a relevant organism, but clinician decides to treat as a deep-seated infection, such as empyema, osteomyelitis, septic arthritis, etc (timepoint: between randomisation and hospital discharge or leading to re-admission to hospital up to 8 weeks from randomisation)
9. Bacteraemia (isolation of a relevant organism from blood) (timepoint: between completion of treatment for this episode of meningitis (including treatment for any relapse if applicable), and hospital discharge or leading to readmission to hospital up to 8 weeks from randomisation)
10. Re-admission after hospital discharge for further treatment for meningitis (timepoint: from hospital discharge to 8 weeks from randomisation)
11. Individual components of the primary outcome:
11.1. Cognitive impairment
11.2. Language impairment
11.3. Vision impairment
11.4. Hearing impairment
11.5. Seizures requiring anticonvulsant medication
11.6. Gross motor impairment
(timepoint for 1-6: at 24 months of age corrected for prematurity in preterm babies; 24 months actual age for term babies)
11.7. Death (timepoint: death up to 24 months of age corrected for prematurity in preterm babies; 24 months actual age for term babies)
12. Behaviour problems assessed using the Child Behavior Checklist for ages 1½ to 5 years (CBCL 1½–5) completed by parent/carer; defined as T score ≥64 for internalising or externalising problems (timepoint: at 24 months of age corrected for prematurity in preterm babies; 24 months actual age for term babies)
13. Child-related quality of life (QoL) assessed using the EuroQoL Toddler and Infant Populations Instrument (EQ TIPS) questionnaire completed by parent/carer (timepoint: At 24 months of age corrected for prematurity in preterm babies; 24 months actual age for term babies and adjusted for 12-month measures)
14. Parental QoL, completed by parent/carer using the EuroQol-5 Dimensions 5 Levels (EQ-5D-5L) questionnaire (timepoint: at 24 months of age corrected for prematurity in preterm babies; 24 months actual age for term babies and adjusted for baseline and 12-month measures)

Completion date

31/08/2033

Eligibility

Key inclusion criteria

1. Babies must fulfil one of the following age-based criteria:
1.1. Babies born at ≥ 37+0 gestational weeks:
1.1.1. Up to and including 3 months from their birth date
OR
1.2. Babies born at 34+0 to 36+6 gestational weeks:
1.2.1. Up to and including 3 months corrected age
OR
1.3. Babies born less than 34+0 gestational weeks:
1.3.1. Are between 32+0 corrected gestational weeks and 3 months corrected age inclusive
AND
1.3.2. Are older than 7 days of age
2. Planned or initiated treatment with antibiotics for suspected or confirmed bacterial meningitis based on having one or more of the following three clinical and/or laboratory features:
2.1. Seizures or bulging fontanelle or altered consciousness (coma)
2.2. Blood C-Reactive Protein (CRP) ≥20 mg/L* AND one or more of:
2.2.1. Raised cerebrospinal fluid (CSF) white cell count (>20/mm3 for neonates ≤28 days post birth; >5/mm3 for babies >28 days post birth)**
2.2.2. CSF protein ≥0.8 g/L**
2.2.3. CSF/blood glucose ratio <0.5
3. Positive CSF Gram stain OR positive CSF polymerase chain reaction (PCR) for a relevant bacterium OR CSF culture for a relevant bacterium

*If CRP is not available then an abnormal procalcitonin (PCT) threshold may be used instead (i.e., ≥0.5 mg/dL)
**When interpreting the results of cerebrospinal fluid (CSF) investigations, take into account red cells in the sample, which may suggest blood contamination or a different diagnosis. In the case of blood contamination if the CSF RBC count is >=1000 cells/µL then CSF WBC and CSF protein should be adjusted
- subtract 1 WBC per 500 RBCs
- subtract 0.01 g/l protein per 1000 RBCs

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

0 Months

Upper age limit

3 Months

Sex

All

Total final enrolment
1123

Key exclusion criteria
1. Where the randomisation cannot occur within 12 hours of the first administration of antibiotics for meningitis, or within 12 hours of the first administration of changed dose/type of antibiotics where antibiotics have been changed in dose or type for newly suspected or confirmed meningitis
2. Previous neurosurgical intervention or shunt
3. Known hypersensitivity to dexamethasone or any of its excipients
4. Previous randomisation into this trial

Date of first enrolment
09/10/2026

Date of final enrolment
30/11/2030

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Canada

Study participating centre
Not provided at time of registration
-
-
England
-

Study participating centre
Not provided at time of registration
-
-
Canada
-

Sponsor information

Organisation
City St George's, University of London

ROR
https://ror.org/047ybhc09

Funder(s)

Funder type

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

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request from the chief investigator Prof. Paul Heath (pheath@citystgeorges.ac.uk). De-identified participant data underlying the results reported in the main publications will be made available after publication of the primary results and will remain available for a defined period thereafter, subject to review and approval of a data access request. Data will be shared with researchers for the purpose of secondary analyses, following review by the trial team and completion of a data sharing agreement. All data will be fully de-identified prior to sharing, and access will be provided in accordance with participant consent and applicable ethical, legal and regulatory requirements.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	15/04/2026	05/10/2026	No	No