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Investigating how genetic differences relate to the risk of maternal fever due to epidural pain relief in mothers during labour

Submission date
26/04/2021

Recruitment status
No longer recruiting

Registration date
29/04/2021

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The project aims to identify women who may be genetically programmed to be more likely to have a fever if they choose epidural (an injection into the back) during labour. By identifying this group of women, we may be able to make their labours more comfortable and less stressful by knowing that they have a higher chance of developing a fever.

Who can participate?
Pregnant women aged over 18 years who request an epidural for labour pain relief

What does the study involve?
Participants will consent to providing a small, single blood sample (as part of the routine blood draw required at the time of the epidural) for genetic analysis. The relationship between one gene that may increase the risk of fever after epidurals and the development of fever and/or prescription of antibiotics plus the outcome of the baby will be recorded.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participating in this study.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
From March 2020 to December 2023

Who is funding the study?
The National Institute for Academic Anaesthesia (UK) and the Obstetric Anaesthetists' Association (UK)

Who is the main contact?
Prof Gareth Ackland
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
270480

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 270480, version 1.0

Study information

Scientific Title
EPIFEVER-2: Mendelian randomisation study of polymorphisms in interleukin-1 receptor antagonist and epidural-related maternal fever.

Acronym
EPIFEVER-2

Study objectives
Polymorphisms in the interleukin-1 receptor antagonist gene promote fever in labouring women receiving epidural analgesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, London – Bloomsbury Research Ethics Committee (MSE Meeting Rooms, Tottenham Court Road, London, W1T 1BB; +44 (0)207 104 8063; bloomsbury.rec@hra.nhs.uk), ref: 20/LO/1213

Study design
Mendelian randomization study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Epidural-related maternal fever in active labour

Interventions
Women are enrolled either in antenatal clinic or on admission to labour ward. A single blood sample is obtained around the time of epidural insertion. Clinical outcomes are collected for the duration of their hospital stay.

Intervention Type
Other

Primary outcome(s)
The incidence of one or both of the following:
1. Maternal temperature >38°C (triggered by RCOG guidelines for two temperatures >37.5°C) recorded as part of their standard care from patient notes at least 4h after epidural analgesia is commenced
2. Prescription of antibiotics during labour before delivery measured from patient notes before delivery

Key secondary outcome(s))
Clinical outcomes for mother and baby measured from patient notes during their hospital stay

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years old
2. Singleton or twin pregnancy
3. Any gestational age
4. Requesting an epidural for labour analgesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
632

Key exclusion criteria
1. Unwilling or unable to give consent
2. Refusal of consent for competent participants
3. Inability to understand written and/ or verbal English
4. Immune/genetic syndromes/mutations
5. Microbiologically proven infection prior to epidural insertion
6. Established pyrexia
7. Intrauterine death

Date of first enrolment
28/04/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Royal London Hospital
Whitechapel Rd
London
United Kingdom
E1 1FR

Study participating centre
Homerton Hospital
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
University College Hospital NHS Trust
235 Euston Rd
London
United Kingdom
NW1 2BU

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Research organisation

Funder Name
National Institute for Academic Anaesthesia

Alternative Name(s)
The National Institute of Academic Anaesthesia (NIAA), NIAA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Obstetric Anaesthetists' Association

Alternative Name(s)
The Obstetric Anaesthetists’ Association (OAA), The OAA, The Obstetric Anaesthetists’ Association, OAA

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2025	09/06/2025	Yes	No
Protocol article		01/05/2022	12/08/2024	Yes	No
HRA research summary			28/06/2023	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes