

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/06/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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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Study website

<http://qmul.ac.uk/ccpmg/>

Contact information

Type(s)

Scientific

Contact name

Prof Gareth Ackland

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

270480

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Epidemiological study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Available from <http://qmul.ac.uk/ccpmg/>

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 measure

The incidence of one or both of the following:

1. Maternal temperature $>38^{\circ}\text{C}$ (triggered by RCOG guidelines for two temperatures $>37.5^{\circ}\text{C}$)

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

Secondary outcome measures

Clinical outcomes for mother and baby measured from patient notes during their hospital stay

Overall study start date

01/03/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

637

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

England

United Kingdom

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

Sponsor details

Empire House
67-75 New Road
London
England
United Kingdom
E1 1HH
+44 (020) 7882 7275
research.governance@qmul.ac.uk

Sponsor type

University/education

Website

<http://www.qmul.ac.uk/>

ROR

<https://ror.org/026zzn846>

Funder(s)**Funder type**

Research organisation

Funder Name

National Institute for Academic Anaesthesia

Alternative Name(s)

NIAA

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Obstetric Anaesthetists' Association

Alternative Name(s)

OAA

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The study protocol and statistical analysis plan will be made publicly accessible on the Queen Mary University of London website <http://www.qmul.ac.uk/>.

Intention to publish date

31/12/2024

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?
HRA research summary			28/06/2023	No	No
Protocol article		01/05/2022	12/08/2024	Yes	No
Results article		14/05/2025	09/06/2025	Yes	No