

EPIFEVER: elucidating molecular mechanisms underlying epidural-related maternal fever

Submission date 24/11/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/07/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

About a third of women in labour receive pain relief via an epidural. When an epidural is performed by an anaesthetic doctor, the anaesthetist places a small plastic tube into a space in the back through which local anaesthetic is infused. A quarter of women who have an epidural in labour develop a high temperature or fever, known as epidural-related maternal fever, but doctors currently do not understand why the fever occurs. Fever during labour can be a real problem. The high temperature results in a more stressful labour for mother and baby. Midwives and obstetricians looking after mothers in labour with a high temperature are concerned that the fever might be due to infection, and these mothers commonly receive antibiotics. It is clear that many women who have an epidural-related maternal fever do not have infection and so the antibiotic treatment is unnecessary. Finally a fever in labour can sometimes lead to women having a Caesarean section or instrumental deliveries because of concerns about the baby. The aim of this study is to find the cause of epidural-related maternal fever. If we can find the cause, we hope to then be able to develop a way to prevent it from happening, and also avoid the use of unnecessary antibiotics.

Who can participate?

We are approaching pregnant women who may receive an epidural for pain relief in labour or for delivery, and non-pregnant women having an epidural for surgery.

What does the study involve?

It is well known that local anaesthetics not only reduce pain, but may also cause immune cells to release substances into the mother's bloodstream. We believe that these substances may be the cause of the fever. We will investigate whether the local anaesthetic causes fever by testing its effects on immune cells collected in blood samples. We would like to collect blood from two groups of women in labour: those receiving an epidural for pain relief and those who do not receive an epidural. We will also collect blood samples from non-pregnant women having surgery who also receive an epidural, so we can find out how epidurals may affect immune cells in women who are not pregnant.

What are the possible benefits and risks of participating?

The information we get from this study may help us to better treat future patients undergoing

epidurals for pain relief and anaesthesia and to prevent epidural-related maternal fever. Every procedure described is a routine part of your care, so there are no additional risks of taking part. We will try as far as possible to collect the blood samples from your existing drip access, which does not carry any risk. If this not possible and we need to collect a blood sample from a vein in your arm.

Where is the study run from?

University College London Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

October 2014 to March 2016

Who is funding the study?

Obstetrics Anaesthetists' Association (OAA)

Who is the main contact?

Dr Gareth Ackland

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

Protocol v1.2

Study information

Scientific Title

EPIFEVER: elucidating molecular mechanisms underlying EPIdural-related maternal FEVER - an observational single-centre study

Acronym
EPIFEVER

Study objectives

Inflammatory mechanisms associated with the development of fever following epidural analgesia started in established labour.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South Central - Oxford A Bristol Research Ethics Committee Centre, 18/08/2014, REC ref: 14/SC/1160

Study design

Observational single-centre study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Epidural-related maternal fever (ERMF)

Interventions

Local anaesthetics not only reduce pain but may also damage immune cells, resulting in substances being released into the mother's bloodstream and causing fever. We will investigate whether the local anaesthetic causes fever through the release of fever-inducing substances by undertaking tests on immune cells obtained from two groups of women: those receiving an epidural for pain relief and those who do not use epidural analgesia. We will also use samples from surgical patients who also receive epidural analgesia. We will insert an IV drip into women /patients which is used routinely as part of their hospital stay, thereby minimizing unnecessary discomfort. While inserting the IV drip a tablespoon of blood will be taken for laboratory tests. 4 hours later another tablespoon of blood will be taken. We will then compare function of immune cells before and after epidural local anaesthetic has been administered. If local anaesthetic is found to affect immune function and be a cause of fever, these results will enable us to identify the cause of fever in individual women in labour and help avoid unnecessary clinical interventions and antibiotic administration in the future.

Intervention Type

Other

Primary outcome(s)

Development of maternal fever; temperature measured pre and 4 hours after onset of epidural analgesia.

Key secondary outcome(s)

Laboratory-based assays of immune function pre- and 4 hours post-epidural (or otherwise)

Completion date

31/03/2016

Eligibility

Key inclusion criteria

>37 weeks gestation, established labour (≥ 2 cm dilated with contractions) and all babies delivered from these women will have outcomes follow up

For female surgical patients >18 years old, all those who have agreed to receive epidural analgesia decided in conjunction with their attending anaesthetist will be eligible

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Total final enrolment

53

Key exclusion criteria

Obstetric patients:

1. No pre-eclampsia or hypertensive disorder
2. No pre-existing immune dysfunction
3. No known infection
4. Not currently on antibiotics
5. Not received NSAID

Female surgical patients:

1. No known infection
2. Not currently on antibiotics
3. Not received NSAID
4. Not pregnant

Date of first enrolment

01/10/2014

Date of final enrolment

31/03/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UCLH NHS Trust

235 Euston Road

London

United Kingdom

NW1 2BU

Sponsor information

Organisation

UCLH NHS Trust

ROR

<https://ror.org/042fqyp44>

Funder(s)

Funder type

Charity

Funder Name

Obstetrics Anaesthetists' Association (OAA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article	results	01/01/2019	03/07/2020	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes