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Preventing fever in women with labour epidurals using a neck warmer

Submission date
21/10/2009

Recruitment status
No longer recruiting

Registration date
11/11/2009

Overall study status
Completed

Last Edited
12/04/2017

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Epidural anaesthesia, often referred to as an epidural, is an injection in the lower back that numbs the nerves and stops mothers from feeling pain during childbirth. It has been known for 25 years that the use of epidural anaesthesia during labour greatly increases the likelihood of a woman developing a high temperature (pyrexia). Pyrexia in labour is associated with brain conditions including neonatal encephalopathy, and in the long term, cerebral palsy. In addition, it is known to increase the proportion of babies admitted to neonatal units for sepsis workup and antibiotic treatment. However, few admissions turn out to be due to infection. Our current theory is that the mother feels cold in the lower half of her body which is anaesthetised, and this causes part of the brain called the hypothalamus to increase her temperature. Studies have suggested that warming the blood going to the hypothalamus by wearing a neck warmer helps to prevent this increase in temperature. The aim of this study is to test whether wearing a neck warmer reduces the maternal temperature rise associated with epidural analgesia in labour.

Who can participate?
Women treated with epidurals for analgesia in labour.

What does the study involve?
Participating women will be randomly allocated to wear a neck collar that is either warmed or left at room temperature. Their temperature will be taken every 4 hours, and the outcome of the labour will be recorded.

What are the possible benefits and risks of participating?
The potential benefit is that mothers allocated to wear a neck warmer may not develop pyrexia, thus avoiding complications for her and her baby. There are no known risks of wearing the neck collar of itself, and when warmed, the neck collar is only 41°C, so there are no anticipated harmful effects.

Where is the study run from?
Chelsea and Westminster Hospital (UK).

When is the study starting and how long is it expected to run for?
The study ran from June 2009 to August 2011.

Who is funding the study?
Chelsea and Westminster Hospital (UK).

Who is the main contact?
Prof Philip Steer
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Contact information

Type(s)
Scientific

Contact name
Prof Philip Steer

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WOG09002CN

Study information

Scientific Title
A randomised clinical trial of the paradoxical cooling effect of a neck warmer in the prevention of maternal pyrexia after insertion and management of low dose epidurals in labour

Study objectives
Wearing a neck warmer will paradoxically reduce the maternal temperature rise associated with epidural analgesia in labour.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Riverside Research Ethics Committee, Charing Cross Hospital, 05/12/2008, ref: 08/H0706/105

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Fever in women with epidural analgesia during labour

Interventions
Intervention group: Neck warmer worn during labour
Control group: No intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Maternal temperature rise during labour

Secondary outcome measures
1. Neonatal temperature at 15 minutes post delivery
2. Change in baseline foetal heart rate on cardiotocography (CTG) from the time that the epidural was sited until delivery
3. Apgar scores at 1 and 5 minutes
4. Percentage of neonates admitted to the Neonatal Intensive Care Unit
5. Number of hours of maternal shivering during labour
6. Percentage of women given paracetamol for fever in labour
7. Mode of delivery
8. Rise in inflammatory markers (IL-6 and C-reactive protein [CRP])

Overall study start date
08/06/2009

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. Women (no age limit) with epidurals for analgesia in labour
2. Nulliparous women (more likely to have labours >6 hours)
3. Cervical dilatation no more than 4 cm (more likely to have labours >6 hours)
4. First labour (more likely to have labours >6 hours)
5. Gestation >36 weeks (more likely to have labours > 6 hours)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
400

Key exclusion criteria
1. Pre-existing fever >37.5 degrees C (fever caused by something other than the epidural)
2. Concurrent maternal disease, including pre-eclampsia (pro-inflammatory state)
3. Multiple pregnancy (physiology of labour exaggerated)
4. Patients receiving steroids or non-steroidal anti-inflammatory drugs within 6 hours (may influence the temperature and interleukin 6 [IL-6])

Date of first enrolment
08/06/2009

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Academic Obstetric Department
London
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SW10 9NH

Sponsor information

Organisation
Chelsea and Westminster NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.chelwest.nhs.uk/

ROR
https://ror.org/02gd18467

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Joint Research Committee grant, Chelsea & Westminster Hospital (UK) (ref: 08/09 SG 015)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration