

Preventing fever in women with labour epidurals using a neck warmer

Submission date 21/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/04/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

Maternal temperature rise during labour

Key secondary outcome(s)

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])

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Academic Obstetric Department

London

United Kingdom

SW10 9NH

Sponsor information**Organisation**

Chelsea and Westminster NHS Foundation Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration