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# Epidural related maternal temperature and neonatal outcome: a randomised controlled study

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|---|---|---|
| **Submission date**<br>30/09/2005 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>21/04/2011 | **Condition category**<br>Pregnancy and Childbirth | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0060148249

# Study information

## Scientific Title

## Study objectives
Maintaining normothermia during labour (including prevention of hyperthermia) will improve outcome in relation to:
1. Short term outcome:
1.1. Obstetric interventions - FBS, emergency caesarean section, instrumental delivery
1.2. Neonatal outcome - neonatal tone and neurobehaviour, neonatal encephalopathy, neonatal sepsis work up and antibiotic treatment, free oxygen radical induced cellular injury
2. Long term outcome - score on Griffiths mental developmental scales at 1 year

Please note that as of 27/06/2008, this record was updated to reflect that this trial was proposed but never started.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Single blind interventional randomised controlled trial.

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Screening

## Participant information sheet

## Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Labour

## Interventions
Maintaining normothermia during labour versus care as usual.

## Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Differences in mean NACS score at 24 +/- 6 hours between the intervention and control group

### Secondary outcome measures
1. Differences in emergency caesarean and instrumental deliveries
2. Foetal intervention - FBS
3. Neonatal adverse outcomes - resuscitation requirements, Apgar score at 1 and 5 minutes, cord gases, feeding difficulties, encephalopathy
4. Neonatal intervention rate with sepsis evaluation and antibiotic treatment
5. Measurement of free oxygen radical metabolites (e.g. malonildehyde) as marker of lipid peroxidation in cord blood

### Overall study start date
01/01/2003

### Completion date
01/11/2004

### Reason abandoned (if study stopped)
This trial was proposed but never started as the research fellow was appointed to a substantive post and left the project.

## Eligibility

### Key inclusion criteria
400 women in each group

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
800

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/01/2003

### Date of final enrolment
01/11/2004

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Dept of Obstetrics & Gynaecology**
London
United Kingdom
SW10 9NH

# Sponsor information

**Organisation**
Department of Health

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Richmond House
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**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Chelsea and Westminster Healthcare NHS Trust (UK)

**Funder Name**
NHS R&D Support Funding (UK)

# 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