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

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

Protocol serial number
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

Primary study design
Interventional

Study design
Single blind interventional randomised controlled trial.

Study type(s)
Screening

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(s)
Differences in mean NACS score at 24 +/- 6 hours between the intervention and control group

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre

Dept of Obstetrics & Gynaecology
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration