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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

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

Sponsor details
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