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Peri-operative fluid warming in elective caesarean section

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 11/10/2011	**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
N0060187568

Study information

Scientific Title

Study objectives
Does providing warmed intravenous fluid at elective caesarean section reduce the incidence of hypothermia and improve maternal thermal comfort?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Caesarean section

Interventions
Warmed intravenous fluid vs no warmed intravenous fluid

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Core body temperature, incidence and severity of shivering and pain (Visual Analogue Scale), thermal comfort score (visual analogue scale), fetal Apgar scores and umbilical cord blood gas measurements (routinely performed at caesarean section)

Secondary outcome measures

1. Shivering
2. Self-reported thermal comfort

Overall study start date
25/10/2006

Completion date
01/12/2007

Eligibility

Key inclusion criteria
Healthy women with uncomplicated single pregnancy of > 37 weeks gestation due for elective caesarean section

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
75 to be recruited consecutively

Key exclusion criteria
1. Pyrexia
2. Inability to take non-steroidal anti-inflammatory (NSAIDs) medication
3. Pre-eclampsia/eclampsia
4. Drug therapy other than antacids and vitamins/minerals
5. Increased risk of intra-operative haemorrhage (eg placenta praevia or accreta).

Date of first enrolment
25/10/2006

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Magill Dept of Anaesthesia, Intensive Care & Pain Management
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

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)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2009		Yes	No