ISRCTN33931714 https://doi.org/10.1186/ISRCTN33931714

Peri-operative fluid warming in elective caesarean section

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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
1. Shivering
2. Self-reported thermal comfort

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Magill Dept of Anaesthesia, Intensive Care & Pain Management
London
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SW10 9NH

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Chelsea and Westminster Healthcare NHS Trust (UK)

Results and Publications

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