

Peri-operative fluid warming in elective caesarean section

Submission date 28/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 11/10/2011	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Steve Yentis

Contact details
Magill Dept of Anaesthesia, Intensive Care & Pain Management
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH
+44 (0)20 8746 8026
s.yentis@imperial.ac.uk

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

United Kingdom

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