ISRCTN32635781 https://doi.org/10.1186/ISRCTN32635781

The effect of ephedrine and phenylephrine on the ED50 of intrathecal bupivacaine required to provide anaesthesia for Caesarean section

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
28/07/2009

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gary Stocks

Contact details
Department of Anaesthesia
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0016176701

Study information

Scientific Title

Study objectives
To evaluate the effect of two vasopressors (drugs that are used to prevent blood pressure falling-hypotension- after spinal anaesthesia) on the dosages of local anaesthetic required to provide successful anaesthesia for caesarean section (CS).

As of 28/07/09 this record was updated. All updates can be found under the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 28/07/09:
Granted February 2006

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

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

Interventions
Patients were randomised to receive
1. either phenylephrine at a rate of 16.6 µg min^1 (concentration 1µg ml^1) or ephedrine at a rate of 1.5 mg min^1 (concentration 90 µg ml^1)
2. varying doses of hyperbaric bupivacaine with fentanyl 25 µg using a double-blinded, up-down sequential allocation design

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ephedrine phenylephrine bupivacaine

Primary outcome measure
The ED50 of intrathecal heavy bupivacaine with 25mcg fentanyl required to achieve a block to touch to Xiphisternum in the ephedrine and phenylephrine groups.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Patients undergoing elective CS with a viable singleton foetus who require regional anaesthesia will be identified.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
70

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Anaesthesia
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 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
Hospital/treatment centre

Funder Name
Hammersmith Hospital 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	01/06/2009		Yes	No