

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

☐ Prospectively registered

☐ Protocol

Registration date
29/09/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/07/2009

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 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 $16.6 \mu\text{g min}^{-1}$ (concentration $1 \mu\text{g ml}^{-1}$) or ephedrine at a rate of 1.5 mg min^{-1} (concentration $90 \mu\text{g ml}^{-1}$)
2. varying doses of hyperbaric bupivacaine with fentanyl $25 \mu\text{g}$ 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