

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

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/07/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

## Study type(s)

Other

## 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  $1.5 \text{ mg min}^{-1}$  (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(s)

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

## Key secondary outcome(s)

Not provided at time of registration

## 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

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### 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

United Kingdom

England

### Study participating centre

Department of Anaesthesia

London

United Kingdom

W6 8RF

## Sponsor information

Organisation

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Hammersmith Hospital 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?
<a href="#">Results article</a>	results	01/06/2009		Yes	No