Prophylactic ephedrine and hypotension during spinal anaesthesia for elective Caesarean section

Recruitment status	Prospectively registered
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	[] Individual participant data
Pregnancy and Childbirth	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Ian Taylor

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

The majority of elective Caesarean section operations are performed using a spinal anaesthetic. One of the common problems with this technique is a fall in the patient's blood pressure - occurring in approximately 70% of cases. At present we closely monitor blood pressure and treat any fall with fluids and/or intravenous drugs (usually ephedrine) as it occurs. The aim of this study is to assess whether or not the frequency of a fall in blood pressure can actually be avoided by the use of ephedrine before a drop occurs. Secondly, if prophylactic ephedrine is of benefit we hope to find out which is the best way to administer the drug: either by a bolus or by a continuous infusion.

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Anaesthesia

Interventions

- 1. Ephedrine infusion
- 2. Ephedrine bolus
- 3. Saline

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

18/11/2002

Completion date

30/06/2003

Eligibility

Key inclusion criteria

A total of 105 patients (35 per group) age >16 years.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

105

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

18/11/2002

Date of final enrolment

30/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Anaesthetics Department Portsmouth United Kingdom PO6 3LY

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

Portsmouth NHS Research and Development Consortium (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 summaryNot provided at time of registration