

Prophylactic ephedrine and hypotension during spinal anaesthesia for elective Caesarean section

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 06/02/2014	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N0187122160

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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/2003

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Anaesthetics Department

Portsmouth

United Kingdom

PO6 3LY

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Portsmouth NHS Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration