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Prophylactic ephedrine and hypotension during spinal anaesthesia for elective Caesarean section

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/02/2014	Pregnancy and Childbirth	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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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 summary

Not provided at time of registration