

Evaluation of equivalent effective dose of ephedrine and phenylephrine in prevention of hypotension after spinal anaesthesia for caesarean section

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|--|---|--|
| Submission date 30/09/2004 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 30/09/2004 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 17/11/2010 | Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436130343

Study information

Scientific Title

Study objectives

The aim of this study is to determine whether ephedrine or phenylephrine or a combination provides the best prophylactic for prevention of hypotension after spinal anaesthesia

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

Randomised controlled trial to determine whether ephedrine or phenylephrine or a combination provides the best prophylactic for prevention of hypotension after spinal anaesthesia.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Efficacy in preventing cardiovascular instability
Uterine arterial blood gas analysis
Incidence of nausea and vomiting under anaesthetic

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2003

Completion date

01/07/2003

Eligibility

Key inclusion criteria

Women who have completed 36 weeks of normal pregnancy, fit and well normally and who are planned to have an elective caesarean section under spinal anaesthesia will be recruited

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

01/07/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Obstetric Anaesthesia Office
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust

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 | 01/01/2006 | | Yes | No |