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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2004		☐ Protocol		
Registration date 30/09/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/11/2010	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr S Saravanan

Contact details

Obstetric Anaesthesia Office Gledhow Wing Leeds Teaching Hospitals NHS Trust Beckett Street Leeds United Kingdom LS9 7TF +44 (0)113 243 3144 r&d@leedsth.nhs.uk

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 summaryNot 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