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A comparison of speed of action of phenylephrine and ephedrine

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 25/03/2020	**Condition category** Pregnancy and Childbirth	

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
N0521113691

Study information

Scientific Title

A comparison of speed of action of phenylephrine and ephedrine

Study objectives
Does phenylephrine allow more rapid control of maternal arterial pressure during obstetric spinal anaesthesia than ephedrine?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Anaesthesia

Interventions
Phenylephrine vs ephedrine

A standardised anaesthetic technique will be used. Maternal arterial pressure will be measured by an automated oscillometric device (Cardiocap II, Datex Instrumentarium) and by a continuous, non-invasive photoplethysmographic device using a finger probe (Finapres 2300, Ohmeda). Boluses of phenylephrine 100 ug or ephedrine 6 mg will be given whenever systolic arterial pressure falls by 15% from the prespinal value. An analog arterial pressure waveform will be recorded using a PowerLab 8sp recording and analysis device (AD Instruments Inc). This time from administration of vasopressor to time of peak effect on arterial pressure will then be analysed.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Phenylephrine and ephedrine

Primary outcome measure
Ttime to peak vasopressor effect on systolic arterial pressure

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/03/2002

Completion date
30/06/2004

Eligibility

Key inclusion criteria
Healthy women having elective caesarean section at term will be recruited.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
No data is available to guide sample size estimations.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
27/03/2002

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University Hospital of North Durham
Durham
United Kingdom
DH1 5TW

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
Government

Funder Name
County Durham and Darlington Acute Hospitals NHS Trust (North) (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