A comparison of speed of action of phenylephrine and ephedrine

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr D Thomas

Contact details

University Hospital of North Durham North Road Durham United Kingdom DH1 5TW

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Ttime to peak vasopressor effect on systolic arterial pressure

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/06/2004

Eligibility

Key inclusion criteria

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

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

27/03/2002

Date of final enrolment

30/06/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre University Hospital of North Durham

Durham United Kingdom DH1 5TW

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

County Durham and Darlington Acute Hospitals NHS Trust (North) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration