

A study to determine the cardiovascular effects of different methods of administering the oxytocic drug Syntocinon

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/05/2009	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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0047119214

Study information

Scientific Title

Study objectives

Can we decrease the unwanted effects of syntocinon, namely hypotension and tachycardia, by slowing down the rate of injection?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Prospective randomised controlled single-centre trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Anaesthesia

Interventions

Bolus injection (bolus group) vs infusion over 5 min (infusion group)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

syntocinon

Primary outcome(s)

Reason for study ie to determine a method that can be used to routinely limit the decrease in blood pressure.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/01/2006

Eligibility**Key inclusion criteria**

Women choosing spinal anaesthesia for elective Caesarean:
15 in control group receiving syntocinon 5 units intravenously (IV) as a bolus after delivery 15 in study group receiving syntocinon 5 units IV continuously over 5 min after delivery

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

01/11/2002

Date of final enrolment

31/01/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Anaesthesia

Birmingham

United Kingdom

B15 2TG

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Birmingham Women's Healthcare NHS Trust (UK)

Results and Publications

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	01/01/2007		Yes	No