ISRCTN71886984 https://doi.org/10.1186/ISRCTN71886984

Method for prevention of oxytocin-induced hypotension in caesarean delivery by mixing of phenylephrine with oxytocin

Submission date
04/03/2012

Registration date
04/04/2012

Last Edited
18/09/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
After a baby is delivered by caesarean section, a drug called Oxytocin (which helps the uterus to contract and reduces bleeding) is administered. Unfortunately, this drug has side effects, one of which is lowering blood pressure temporarily. The effect of this drop in blood pressure can be counteracted by administering another drug called Phenylephrine. We are investigating if giving both of these drugs together will reduce or prevent this fall in blood pressure.

Who can participate?
Any woman aged between 18 and 35 years undergoing elective caesarean section under spinal anaesthesia.

What does the study involve?
Participants will be randomly allocated into one of three groups. One group will receive oxytocin plus saline solution, the second group will get oxytocin plus 100 micrograms of Phenylephrine, and the third group will get oxytocin plus 200 micrograms of Phenylephrine. After the delivery of the baby, the medication will be administered and blood pressure will be measured every minute for five minutes. If the blood pressure drops in any of the groups, phenylephrine is given as appropriate.

What are the possible benefits and risks of participating?
The information and data collected from this study will help us to find the best way to prevent the drop in blood pressure caused by Oxytocin, hence improving care for women undergoing caesarean sections. Both drugs in this study are not new or experimental. They are being used routinely worldwide. We are only modifying the way we use them. The only discomfort that the patient may feel is the repeated blood pressure measurement on your arm every minute initially.

Where is the study run from?
Raja Isteri Pengiran Anak Saleha (RIPAS) Hospital, Brunei.

When is the study starting and how long is it expected to run for?
The study ran from October 2011 to September 2012.

Who is funding the study?
Ministry of Health and RIPAS hospital, Brunei.

Who is the main contact?
Dr A.B.M. Kamrul Hasan
drkamrul@dhaka.net

Contact information

Type(s)
Scientific

Contact name
Dr ABM Kamrul Hasan

Contact details
27-B, Mabohai Apartment
Simpang 10
Jalan Jawatan Dalam
Bandar Seri Begawan
Brunei Darussalam
BA 1111
+673 (0) 868 4579
drkamrul@dhaka.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevention of oxytocin-induced hypotension in caesarean delivery by co-administration of phenylephrine with oxytocin: a prospective randomised double-blind controlled study

Study objectives
Co-administration of phenylephrine with oxytocin will reduce the incidence of oxytocin-induced hypotension after caesarean delivery.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Medical and Health Research & Ethics Committee, Ministry of Health, Brunei Darussalam, 16/06 /2011, ref: MHREC/MOH/ 2011/9 (7)

Study design
Prospective randomised double-blind control study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Elective caesarean section under spinal anaesthesia

Interventions
After written informed consent of the patients, 200 ASA class I and ll women having elective caesarean section under spinal anaesthesia will be given either a dose of 10 IU Oxytocin plus placebo or 10 IU Oxytocin plus 100 or 200 mcg of phenylephrine in a prospective, randomised double-blind fashion. Randomisation will be done by using Microsoft Excel generated random number allocations. Opaque envelopes containing group assignments will be used to ensure blinding of the investigators. The study and control medicine will be prepared before surgery and will be diluted with 0.9% normal saline up to a volume of 3 ml by an anaesthetist not involved in the study.

In the preoperative period, a large bore IV canula will be inserted. All patients will receive 500 ml of Haemaccele within before 30 minutes of spinal anaesthesia. Before spinal anaesthesia, standard monitoring (Datex Engstrom A/S 3, Helsinki, Finland) - Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP) and Pulse Oximetry will be commenced. Measurement of NIBP and heart rate will be taken at 1 minute intervals from the time of oxytocin administration to next 5 minutes, and thereafter at 5 minutes intervals until the end of surgery. The last measurement of NIBP and heart rate before oxytocin administration will be considered as the baseline for subsequent changes.

Spinal anaesthesia will be performed at the L3-4 interspace with the patient in the sitting position. All subjects will be given 2 ml of 0.5% Bupivacaine Heavy plus 25 mcg of Fentanyl delivered through a 25 gauge sprotte needle with introducer to achieve uniform performance. The protocol medicine will be administered as an IV bolus over a time period of 5 to 10 seconds

after clamping of the umbilical cord and delivery of the fetus. Immediately after the bolus, a separate infusion of oxytocin 20 IU in 500 ml of 0.9% normal saline will be continue over a 4-hour period (at the rate of 5 IU per hour).

Hypotension will be defined as a systolic blood pressure of less than 20% of the baseline blood pressure. Tachycardia will be defined as a maternal heart rate of more than 120 beats per minute. Crystalloid solution (Lactated Ringers Solution) will be infused during the intraoperative period with the aim of using a total crystalloid fluid of 1 litre. Each hypotension will be treated with an IV bolus of phenylephrine and both hypotensive episode and intraoperative fluid management will be at the discretion of the supervising anaesthetist who will not be involved in this study.

GROUPING OF THE PATIENTS:
Group A: Control group: 10 IU of Bolus Oxytocin plus Placebo
Group B: Study group: 10 IU of Bolus Oxytocin plus 100 mcg of Phenylephrine
Group C: Study group: 10 IU of Bolus Oxytocin plus 200 mcg of Phenylephrine

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxytocin, phenylephrine

Primary outcome measure
Percentage drops in blood pressure (BP) below 20% of baseline after intravenous injection of oxytocin in each arm of study

Secondary outcome measures
Percentage of patient having nausea and vomiting after oxytocin in each arm of study

Overall study start date
01/10/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. American Society of Anesthesiologists (ASA) class l and ll undergoing elective caesarean section
2. Age between 18 to 35 years
3. Body mass index (BMI) less than 35 kg/m2
4. Spinal anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Placenta previa
2. Thrombocytopenia
3. Coagulopathies
4. Previous major obstetrics haemorrhage (more than 1000 ml)
5. Known fibroid
6. Receiving anticoagulant therapy
7. Anemia (hemoglobin less than 9 g/dl)
8. Body mass index greater than 35 kg/m2
9. Preeclampsia
10. Cardiac, respiratory and renal disease
11. Known allergy to any protocol medicine

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Brunei Darussalam

Study participating centre
27-B, Mabohai Apartment
Bandar Seri Begawan
Brunei Darussalam
BA 1111

Sponsor information

Organisation

Ministry of Health (Brunei)

Sponsor details
Commonwealth Drive
Bandar Seri Begawan
Brunei Darussalam
BB 3910

Sponsor type
Government

Website
http://www.moh.gov.bn

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Brunei)

Funder Name
Raja Isteri Pengiran Anak Saleha Hospital (RIPAS) Hospital (Brunei)

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