ISRCTN10193593 https://doi.org/10.1186/ISRCTN10193593

Different routes and forms of uterotonics for treatment of retained placenta

Submission date
08/05/2014

Recruitment status
No longer recruiting

Registration date
03/06/2014

Overall study status
Completed

Last Edited
14/12/2015

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Placenta retained inside the uterus after birth is one of the major factors for excessive bleeding (haemorrhage) after childbirth. Identifying a simple way to deliver the placenta without the need for manual removal under general anaesthesia will have a positive impact for the patient and her treating doctor. Utertonics are agents used to induce contraction of the uterus. The aim of our study is to compare the effects of three different utertonics given by three different routes on the need for manual removal of placenta and/or the quantity of blood loss among patients with retained placenta. We also aim to find out if there are any advantages of certain routes over the others.

Who can participate?
Women giving birth at the participating hospitals can take part in this study.

What does the study involve?
The participants will be randomly allocated to one of three groups. Group 1 receives oxytocin through the umbilical cord vein, Group 2 receives carbetocin through the vein in the arm, and Group 3 receives misoprostol placed under the tongue.

What are the possible benefits and risks of participating?
The medication given can help the delivery of the placenta so that manual removal under general anaesthesia can be avoided. No risks are expected for participants.

Where is the study run from?
The study is run from Menoufiya University Hospitals in Egypt and Al-Hayat National Hospital in Saudi Arabia.

When is the study starting and how long is it expected to run for?
June 2014 to January 2016.

Who is funding the study?
Menoufiya University Hospital (Egypt) and Al-Hayat National Hospital (Saudi Arabia).

Who is the main contact?
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Contact information

Type(s)
Scientific

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101

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Different routes and forms of uterotonics for treatment of retained placenta: a randomized clinical trial

Study objectives
The aim of our study is to compare three different forms of uterotonics (oxytocin, carbetocin and misoprostol) given by three different routes (intra-umbilical, intravenous and sublingual, respectively) on the incidence of manual removal of placenta (MROP) and/or the quantity of blood loss among patients with retained placenta (RP) and also to exploit the advantage of a certain route over the others if any.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Obstetrics and Gynecology Departments in two collaborative centers (Menoufiya University Hospitals in Egypt and Al-Hayat National Hospital in Saudi Arabia), 06/05/2014

Study design

Prospective randomized non-blind non-placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Retained placenta

Interventions
The enrolled participants will be allocated randomly into three groups. The trial allocation sequence for all cases enrolled will be developed using a computer-generated random number table. Sequentially numbered sealed opaque envelops will be used to hide the generated allocation sequence. Each envelope contains a single assignation to either Group A, Group B or Group C. Women are allocated to one of the following three regimens by opening one of the sequentially numbered sealed opaque envelopes.

Group A women will receive oxytocin (Syntocinon®, Novartis Pharma AG, Basel, Switzerland) via fetal cord umbilical vein. The umbilical cord is re-cut to achieve a clean end through which a nasogastric tube is passed into the umbilical vein until resistance is felt then withdrawing 5 cm of it to allow for any divisions of the vein prior to its insertion in the placenta. 30 IU oxytocin is diluted in 20 ml of normal saline and injected directly down the nasogastric tube in the umbilical vein. After the injection of the solution, the cord is clamped with the catheter in position for 10 minutes prior to trying controlled cord traction.

Group B women will receive Carbetocin (Pabal®, Ferring GmbH, Kiel, Germany). One ampoule is diluted in 10 ml normal saline and administered slowly intravenously over 30-60 seconds.

Group C women will receive sublingually 400 ug of misoprostol (Cytotec®, GD SEARLE LLC, USA). The envelopes will be prepared by the medical research officer in both hospitals and all authors will be unaware of the envelopes' contents.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxytocin, carbetocin, misoprostol

Primary outcome(s)
1. Delivery of the placenta within 30 minutes following drug administration (either spontaneously or following controlled cord traction)
2. The need for MROP

Key secondary outcome(s))
1. Post-partum hemorrhage defined as drop in the hemoglobin of 2 g/dl between the pre-randomization level or that taken at least 2 weeks before delivery and the hemoglobin

measured 24 hours after delivery
2. Need for blood transfusion at any time before discharge from the hospital
3. Need for additional uterotonic agents to control post-partum hemorrhage
4. Need for uterine curettage

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1. Booked or un-booked patients who deliver in the study hospitals or those who are transferred to them after delivering elsewhere
2. Gestational age of 28 weeks or more (updated 11/08/2015: was previously 20 weeks or more)
3. Singleton pregnancies
4. ≥30 minutes interval after the delivery of the baby provided that our routine active management of the third stage was implemented

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Maternal hemodynamic instability requiring immediate intervention (pulse > 100 beats per minute, systolic blood pressure <100 mmHg, diastolic blood pressure reduction more than 20 mmHg)
2. Severe postpartum hemorrhage requiring immediate intervention
3. History of RP or MROP in any previous delivery
4. Vaginal birth after previous cesarean scar
5. Associated medical disorders (e.g., pre-eclampsia, gestational hypertension, pre-gestational and gestational diabetes, cardiac diseases)
6. Placenta previa in the current pregnancy or previous pregnancies
7. Stillborn baby
8. Snapped umbilical cord
9. Known uterine anomalies

Date of first enrolment
08/06/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Egypt

Saudi Arabia

Study participating centre
Al-Hayat National Hospital
Khamis Mushyat
Saudi Arabia
101

Study participating centre
Menoufiya University Hospital
Shebin Elkom
Egypt
101

Sponsor information

Organisation
Al-Hayat National Hospital (Saudi Arabia)

Organisation
Menoufiya University Hospital (Egypt)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Menoufiya University Hospital (Egypt)

Funder Name

Al-Hayat National Hospital (Saudi Arabia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration