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Carbetocin versus oxytocin for the prevention of post-partum hemorrhage in caesarean section

Submission date
10/03/2016

Recruitment status
No longer recruiting

Registration date
20/04/2016

Overall study status
Completed

Last Edited
13/04/2016

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
A caesarean section is an operation to deliver a baby. There is a risk of heavy bleeding after caesarean section, known as postpartum haemorrhage (PPH). The aim of this study is to evaluate the effectiveness and safety of the drug carbetocin in comparison to oxytocin at preventing PPH in the third stage of labour (when the placenta is delivered) after caesarean section.

Who can participate?
Women with a single pregnancy undergoing cesarean delivery at term

What does the study involve?
Participants are randomly allocated to be treated with either intravenous (into a vein) carbetocin or intramuscular (into a muscle) oxytocin in the third stage of labour. The amount of blood lost, the need for additional drugs and blood transfusions, and adverse effects are recorded in both groups.

What are the possible benefits and risks of participating?
The possible benefit is control of bleeding after cesarean section, which could otherwise lead to postpartum hemorrhage with fatal outcome. There is a small risk of minor side effects.

Where is the study run from?
Sir Salimullah Medical College and Mitford Hospital (Bangladesh)

When is the study starting and how long is it expected to run for?
January to December 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Prof Ferdousi Begum
2. Dr Shakila Yesmin

Contact information

Type(s)
Scientific

Contact name
Prof Ferdousi Begum

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SSMCH201476

Study information

Scientific Title

Carbetocin versus oxytocin for the prevention of post-partum hemorrhage in caesarean section: a randomised controlled trial

Study objectives
Carbetocin is more effective than oxytocin in the active management of third stage of labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of Sir Salimullah Medical College, Dhaka, Bangladesh, 22/12 /2014, Ref no- SSMC /2014/76

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Third stage of labour

Interventions
64 pregnant women who had undergone cesarean delivery were randomized into two groups. One group of patients received intravenous 100 microgram carbetocin and another group of patients received intramuscular 10 IU oxytocin in the third stage of labour.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Carbetocin, oxytocin

Primary outcome measure

Efficacy of carbetocin over oxytocin for the management of third stage of labor

Secondary outcome measures
1. The need for additional uterotonic within 24 hours of delivery after carbetocin or oxytocin administration
2. The amount of blood loss in 24 hours after delivery after carbetocin or oxytocin administration
3. The need for blood transfusion during the first 24 hours after delivery after carbetocin or oxytocin administration
4. The adverse effects of carbetocin and oxytocin after administration

Overall study start date
01/01/2015

Completion date
01/12/2015

Eligibility

Key inclusion criteria
Women with a single pregnancy undergoing cesarean delivery at term

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
64

Key exclusion criteria
1. Placenta praevia
2. Multiple gestations
3. Placental abruption
4. Hypertensive disorders in pregnancy
5. Preeclampsia
6. Cardiac, renal or liver diseases
7. Epilepsy
8. Women with history of hypersensitivity to carbetocin according to the Br National Formulary

Date of first enrolment
01/01/2015

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Bangladesh

Study participating centre
Sir Salimullah Medical College and Mitford Hospital
Dhaka
Bangladesh
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Sponsor information

Organisation
Beacon Pharmaceuticals Ltd (Bangladesh)

Sponsor details
153-154 Tejgaon I/A
Dhaka-1208
Dhaka
Bangladesh
-

Sponsor type
Industry

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Next issue of FIGO journal

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request