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

Submission date	Recruitment status	Prospectively registered
10/03/2016	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/04/2016	Completed	Results
Last Edited	Condition category	Individual participant data
13/04/2016	Pregnancy and Childbirth	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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Contact details

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Type(s)

Scientific

Contact name

Dr Shakila Yesmin

Contact details

Department of Obstetrics and Gynecology Sir Salimullah Medical College and Mitford Hospital Dhaka Bangladesh

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

Completion date

01/12/2015

Eligibility

Key inclusion criteria

Women with a single pregnancy undergoing cesarean delivery at term

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Sponsor information

Organisation

Beacon Pharmaceuticals Ltd (Bangladesh)

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type Date created Date added Peer reviewed? Patient-facing? **Details**

Participant information sheet 11/11/2025 11/11/2025 No Participant information sheet

Yes