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

Submission date 10/03/2016	<b>Recruitment status</b> No longer recruiting	Prospectively registered     Protocol
Registration date	Overall study status	<ul> <li>Statistical analysis plan</li> </ul>
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** Popular Diagnostic centre Shyamoli Dhaka Bangladesh

**Type(s)** Scientific

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

## 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

The amount of blood loss in 24 hours after delivery after carbetocin or oxytocin administration
 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

## 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