

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effects of carbetocin versus oxytocin in preventing postpartum hemorrhage in patients undergoing elective cesarean sections

Protocol summary

Study aim

To evaluate the effect of Carbetocin versus Oxytocin in the prevention of postpartum hemorrhage (PPH) in patients undergoing elective cesarean section at Kosar Hospital in Urmia in the year 1404 (2025).

Design

This is a phase 3 randomized, single-blind, parallel-group clinical trial comparing Carbetocin and Oxytocin, conducted on 184 patients.

Settings and conduct

A total of 184 patients (92 in each of the Carbetocin and Oxytocin groups) will be selected from among candidates undergoing elective cesarean section. The study will be conducted at Kosar Hospital in Urmia in the year 1404 (2025). Baseline patient information—including age, gravidity, parity, history of abortion, gestational age, birth weight, body mass index (at the first prenatal visit), history of myoma, presence of PROM (premature rupture of membranes), meconium-stained amniotic fluid, and fetal distress—will be recorded and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: "Elective cesarean candidates: nulliparous, breech, or one prior cesarean, with written consent." Exclusion Criteria: : Diabetes mellitus ,Hypertension ,Multiple pregnancies ,Polyhydramnios ,Fetal macrosomia ,Maternal renal, cardiac, or hepatic diseases ,Maternal coagulation disorders ,Placental adherence disorders (placenta accreta, increta, or percreta)

Intervention groups

Intervention Group A (Carbetocin Group), Group B (Oxytocin Group)

Main outcome variables

Primary Outcomes: volume of blood loss during cesarean section (from placental delivery to uterine suturing), blood loss during the first 2 hours post-cesarean. Requirement for blood product transfusion within 48 hours after surgery. Changes in hemoglobin levels.

Changes in hematocrit levels. Secondary Outcomes: Patients' vital signs. Need for additional interventions to control bleeding, Drug-related adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140420017365N5**

Registration date: **2025-07-27, 1404/05/05**

Registration timing: **prospective**

Last update: **2025-07-27, 1404/05/05**

Update count: **0**

Registration date

2025-07-27, 1404/05/05

Registrant information

Name

Fatemeh Bahadori

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-06, 1404/05/15

Expected recruitment end date

2026-02-04, 1404/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of carbetocin versus oxytocin in preventing postpartum hemorrhage in patients undergoing elective cesarean sections

Public title

Investigation of the effects of carbetocin versus oxytocin in preventing postpartum hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients who are candidates for elective cesarean section, including nulliparous women, breech presentations, and those with a history of one previous cesarean, provided that they have signed an informed written consent.

Exclusion criteria:

diabetes hypertension multiple pregnancy polyhydramnios macrosomia kidney, heart and liver diseases Maternal coagulation disorders placental attachment disorders (accreta, increta and percreta)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **184**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be carried out using the convenience sampling method among patients who are candidates for elective cesarean section and do not meet any of the exclusion criteria. Random allocation to the study groups will be performed using the permuted block randomization method in two groups with a block size of four (Sealed Envelope: 65871875657749). The randomization process will be based on a pre-designed Excel file corresponding to the determined sample size. A total of 46 blocks of four will be generated, each containing two assignments to Group A and two to Group B in varying sequences (e.g., BBAA). Each patient within a block will be assigned a unique identification code, which will be known only to the clinical evaluator responsible for assessing patient outcomes. This code will be recorded on the patient's data collection form. At the time of enrollment, patients will only be assigned the unique code. The intervention group will be revealed at the time of drug administration by the clinical evaluator, who will determine which of the two study drugs the patient will receive.

Blinding (investigator's opinion)

Single blinded

Blinding description

Allocation to the study groups will be performed randomly using the permuted block method in two groups with a block size of 4 (Sealed Envelope: 65871875657749). Random allocation will be done using a pre-designed Excel file based on the calculated sample size. A total of 46 blocks, each consisting of 4 allocations (with two assignments to group A and two to group B, e.g., BBAA), will be used. Each patient within a block will be assigned a unique identification code. This code will only be known to the clinical evaluator and will be recorded in the patient data collection form. Upon entry into the study, only this unique code will be assigned to the patient. The intervention group (i.e., the medication to be administered) will then be revealed at the time of drug administration by the evaluator who is aware of the allocation. Patients will remain blinded to the group assignments. In the random sampling process, each patient will be assigned a unique code that will be kept confidential. As described in the sampling and randomization method, each block and group assignment is associated with a unique code indicating the group. In this way, patients will receive only the code at study entry, and the assigned intervention will be determined at the appropriate time by the clinical evaluator.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

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Urgent Street, Resalat Blvd, Urmia, Iran

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Approval date

2025-06-25, 1404/04/04

Ethics committee reference number

IR.UMSU.REC.1404.112

Health conditions studied

1

Description of health condition studied

Blood loss after cesarean

ICD-10 code

O72

ICD-10 code description

Postpartum hemorrhage

Primary outcomes

1

Description

Intraoperative blood loss

Timepoint

from placental delivery to uterine suturing

Method of measurement

Measurement of Blood Loss: Blood volume will be measured by recording the amount collected in the suction device and weighing all surgical gauzes and laparotomy sponges before and after surgery. A non-absorbent plastic sheet will be placed at the beginning of the procedure, and all pre-weighed materials will be collected on it. After surgery, the materials will be reweighed. The difference in weight (in grams) will be recorded, with each gram considered equivalent to 1 mL of blood loss.

2

Description

Postoperative blood loss during the first 2 hours after cesarean section

Timepoint

during the first 2 hours after cesarean section

Method of measurement

Blood Volume and Blood Loss Estimation: The blood volume in non-pregnant women is calculated using the following formula: $\text{Blood volume (mL)} = (50 \times \text{height in inches}) + (25 \times \text{weight in pounds}) / 2$. In pregnancy, blood volume increases by approximately 30–60% (about 1500–2000 mL) in women with average body size and no hypovolemia. During delivery, pregnant women can typically tolerate blood loss nearly equal to this additional volume without a significant drop in hematocrit. If blood loss is less than the pregnancy-induced blood volume increase, hematocrit remains stable in the acute phase and for the first few days postpartum. However, if the postpartum hematocrit is lower than the admission hematocrit, the estimated blood loss corresponds to the amount of volume lost, with every 500 mL of blood loss resulting in approximately a 3% decrease in blood volume. In this study, blood loss for each patient will be estimated using the difference between pre-delivery and 24-hour postpartum hematocrit levels.

3

Description

Need for blood product transfusion within 48 hours post-surgery

Timepoint

within 48 hours post-surgery

Method of measurement

The requirements for transfusion of packed cells (P.C), fresh frozen plasma (FFP), and platelets will be documented within 48 hours following the surgical procedure.

4

Description

changes in hemoglobin level

Timepoint

within 48 hours postpartum

Method of measurement

Hemoglobin levels will be assessed at baseline (on the day of admission before surgery) and at 6-hour intervals up to 48 hours postpartum in both groups receiving oxytocin and carbetocin.

5

Description

changes in hematocrit levels

Timepoint

within 48 hours postpartum

Method of measurement

Hematocrit levels will be evaluated at baseline (on the day of admission before the procedure) and at 6-hour intervals up to 48 hours postpartum in both groups receiving oxytocin and carbetocin.

Secondary outcomes

1

Description

patients vital signs

Timepoint

before the intervention, then every 10 minutes for two times, followed by every 30 minutes for two times, and subsequently every 30 minutes for up to two hours

Method of measurement

Patients' vital signs — including heart rate, systolic blood pressure, diastolic blood pressure, and body temperature — will be recorded before the intervention, then every 10 minutes for two times, followed by every 30 minutes for two times, and subsequently every 30 minutes for up to two hours. Blood pressure and heart rate will be continuously monitored and documented.

2

Description

need for hemorrhage control

Timepoint

within 48 hours postpartum.

Method of measurement

The indications for administration of anticoagulant drugs and/or surgical interventions will be evaluated within 48 hours postpartum.

3

Description

adverse drug effects

Timepoint

first 6 hours after surgery.

Method of measurement

The incidence of headache, fever, chills, nausea, and vomiting will be assessed in all patients during the first 6 hours after surgery.

Intervention groups

1

Description

Intervention group: Intervention Group A (Carbetocin Group): In the carbetocin group, to minimize the risk of hypotension caused by spinal anesthesia, all patients will receive an infusion of 500 mL of 0.9% normal saline prior to the start of surgery. Blood pressure and heart rate will be checked and recorded before drug administration. Following placental delivery, 100 micrograms of intravenous carbetocin will be administered. After drug administration, blood pressure and heart rate will be monitored every 10 minutes for two times, followed by every 30 minutes for two times, and then every 30 minutes for up to two hours. Vital signs will be measured automatically using a pulse oximetry device, and the recorded data will be entered into patient data collection forms by the principal investigator.

Category

Prevention

2

Description

Intervention group: Intervention Group B (Oxytocin Group): In the oxytocin group, following placental delivery, an intravenous infusion of 30 units of oxytocin in 1 liter of 0.9% normal saline will be initiated and administered over 2 hours while the patient remains in the operating room and recovery area. After transfer to the ward, an additional 20 units of oxytocin will be infused over a period of 8 hours. Following drug administration, blood pressure and heart rate will be monitored every 10 minutes for two times, followed by every 30 minutes for two times, and then every 30 minutes for up to two hours. Vital signs will be automatically measured using a pulse oximeter device, and all recorded parameters will be entered into the patient data collection forms by the principal investigator.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Fatemeh Bahadori

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Horiyeh Gasempoursore

Position

Rezident of gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

non-demographic data files , including the main study variables ,are published online in excel format.

When the data will become available and for how long

The data will be published after the publication of the protocol paper and the original paper of the study results by the corresponding researcher.

To whom data/document is available

The data will be available online without any request.

Under which criteria data/document could be used

For analysis and study by other interested researchers.

From where data/document is obtainable

The data will be available online.

What processes are involved for a request to access data/document

The data will be available online without any request.

Comments