Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

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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 patientsundergoing 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
Street address
Urgent Street , Resalat Blvd , Urmia , Iran
City
urmia
Province
West Azarbaijan
Postal code
57147833
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:Blood volume (mL) = (50 × height in inches) + (25 × weight in pounds) / 2In 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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Fax
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Email
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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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Street address
Deputy of research and technology building , University headquarters , End of Emergency Alley , Resalat boulevard , Urmia
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Email
saber@umsu.ac.ir
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
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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