Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison between effects of Carbetocine and Syntometrin on postpartum hemorrhage prevention after cesarean section

Protocol summary

Summary

1- Objectives: Comparison between effects of Carbetocine and Syntometrin on postpartum hemorrhage prevention after cesarean section. 2- Design: Randomized single-blind clinical trial, without placebo control, single center trial recruitment, in the third Trial phase. 3- Setting, conducting and inclusion criteria: 90 pregnant women, candidate for primary cesarean section or experienced one with spinal anesthesia at Emam Ali hospital in Zahedan, are provided with explanations of methods for postpartum hemorrhage prevention after cesarean section. Then, the patients and their spouses fill out the consent forms. They are randomly assigned to two groups: 4- Intervention: The first group receives 30 units of oxytocin in 1 litter crystalloid, with 10cc/min rate, right after clamping the umbilical cord. Subsequently, they receive 30, 20 and 10 units of oxytocin IV infusion during the first 8 hours, second 8 hours and last 8 hours, respectively . The second group receives 0.5 ml Carbetocin IV directly, Equivalent to 50 microgram once, right after clamping the umbilical cord. 5- Exclusion criteria: patients with risk factors of PPH or other reason of PPH - except atonia - will exit trial. Also, presence of preeclampsia, hypotension, heart disease, and asthma will exclude a patient. 6- Main outcome: All patients are assessed 2,12, and 24 hours after delivery for uterine tonicity and blood pressure. 6 and 12 hours after delivery, hemoglobin is checked for estimation of postpartum hemorrhage. The two intervention groups are compared for the need of uterotonic drugs and the rate of side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050919644N1**
Registration date: **2015-05-09, 1394/02/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-05-09, 1394/02/19

Registrant information

Name
Seyede Faemeh Mahdavi Salimi
Name of organization / entity
Zahedan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research,zahedan university of medical science

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between effects of Carbetocine and Syntometrin on postpartum hemorrhage prevention after cesarean section

Public title

Carbetocin versus Oxytocin for prevention of postpartum hemorrhage at cesarean section

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Pregnant women with single pregnancy one previous cesarean section or primary cesarean and candidate for cesarean delivery & application of spinal anesthesia. 5- Exclusion criteria: Other reason of PPH except atonia; Presence of preeclampsia; hypotension; heart disease and asthma; Presence of risk factor of PPH such as uterine fibroid؛ previous myomectomy؛ placenta previa؛ past history of PPH؛ chorioamnionitis; fetal macrosomia and fetal malformations associated with polyhydramnios
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Morality Committee of Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Daneshgah street, Zahedan
City
Zahedan
Postal code
Approval date
2014-08-03, 1393/05/12
Ethics committee reference number
6804

Health conditions studied

1

Description of health condition studied
postpartum hemorrhage
ICD-10 code
Z39
ICD-10 code description
Postpartum care and examination

Primary outcomes

1

Description
Hemoglobin level
Timepoint
Before and 6 and 12hours after cesarean delivery
Method of measurement
Hemoglobine assessment

Secondary outcomes

1

Description
Uterine tone
Timepoint
2 and 12 and 24 hours after cesarean delivery
Method of measurement
Assessment of uterine tone

2

Description
Need to adminestration of utertonic drug
Timepoint
During 24 hours after cesarean delivery
Method of measurement
Dosage and amount of drug

3

Description
Adverse effects
Timepoint
During 24 hours after cesarean delivery
Method of measurement
Observation of adverse effects

Intervention groups

1

Description
30 unite Syntometrine in 1 liter crystaloid 10cc /min after clamp of umbilical cord then 30 unite in 8 hours ,20 unite in 8 hours & then 10 unite in 8 hours later Syntometrine IV infusion
Category
Prevention

2

Description
0.5 ml Carbetocin IV directly Equivalent 50 micro gram once after clamp of umbilical cord
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali hospital
Full name of responsible person
Dr Seyede Fatemeh Mahdavi Salimi
Street address
Emam Ali hospital, salamat street, Daneshgah street, Zahedan
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Zahedan University of Medical Science
Full name of responsible person
Dr Hoshang Rafigh Dost
Street address
Vice Chancellor for research, Zahedan University of Medical Sciences, Daneshgah street, Zahedan
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Zahedan University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Emam Ali hospital
Full name of responsible person
Dr Seyede Fatemeh Mahdavi Salimi
Position
Resident of Obstetric and Gynecology
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty