Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Comparative Effects of Normal Oxytocin Dose with 80 Unit Dose on Preventing Uterine Atony after Cesarean Delivery

Protocol summary

Summary

ABSTRACT Background: postpartum hemorrhage is one of the main cause of mothers' death after pregnancy mostly in developing country. The frequency of postpartum hemorrageaftge after natural pregnancy and cesarean are respectively reported 2-4% and 6%. Uterine atony is the cause of more than 75% to 90% postpartum hemorrhage that leads to mother's death if it is neglected. Oxytocin is one of the most common and low risk drug for prevention of uterine atony. The main goal of this study is to compare two regiments of oxytocine: one with high dose and the other with normal one to prevent uterine atony. Methods: the study has been done via clinical trial method on 150 pregnant women who referred to Ali-ebn-abitaleb and Khatam-o-alanbia hospitals for elective cesarean delivery in Zahedan, Iran. The society is randomly divided into two groups. The patients having risk factors of uterine atony and other risk factors of postpartum hemorrhage were omitted from the list. Oxytocin with 80 and 30 dose was respectively infused in 500 cc ringer serum for control and witness group immediately after infant emersion during a period of 30 minutes. Decline of hemoglobin 6 and 24 hours after cesarean section, uterine atony, blood infusion and extra uterotonic drug needs after oxytocin infusion have been measured for both groups. The data has been analyzed using chi-X2 via Spss software. Results: the result indicates that there exist meaningful differences between control and witness group in uterine atony, extra utertonic drug need while and after surgery(0 as compared with 22.6% and Pvalue=0) ; whereas, there were no significant difference between control ant trial group in decline of hemoglobin 6 and 24 hours after cesarean section (Pvalue respectively 0.714 and 0.231). It means that oxytocin infusion with 80 dose has a good impact on the above four variances. Conclusions: considering the above mentioned results, it is recommended that oxytocin infusion with 80 dose during a period of 30 minute could be a good substitution for oxytocin infusion with 30 dose for prevention of uterine atony during and after cesarean delivery especially when utertonic drug is not accessible and in the case of counter indication of other drugs' use. Key words: postpartum hemorrhage- oxytocin- uterine atony- cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020921015N1**
Registration date: **2015-02-28, 1393/12/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-28, 1393/12/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date
2014-09-23, 1393/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Comparative Effects of Normal Oxytocin Dose with 80 Unit Dose on Preventing Uterine Atony after Cesarean Delivery

Public title
Effects of Oxytocin on Uterine Atony
Purpose
Treatment
Inclusion/Exclusion criteria
The women having the following risk factors of uterine atony were excluded from the study, such as more than seven parity, high blood pressure, preeclampsia, Multiple pregnancies,polyhydramnios,hemoglobin less than 10 mg per deci liter, systolic blood pressure less than 100 mmHg, placenta previa, those who have long surgery and need to blood transfusion,
Age
From **18 years** old to **39 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical School, Zahedan University of Medical sciences
Street address
Medical School, Zahedan University of Medical sciences, Dr.Hesabi SQ.
City
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Postal code
9816743463
Approval date
2014-03-06, 1392/12/15
Ethics committee reference number
6126

Health conditions studied

1

Description of health condition studied
Uterine Atony after Cesarean Delivery
ICD-10 code
O62.2
ICD-10 code description
Atony of uterus

Primary outcomes

1

Description
uterine atony
Timepoint
after cesarean
Method of measurement
based on diagnostic test

Secondary outcomes

1

Description
hemoglobin drop
Timepoint
6 hours and 24 hours after surgery (after oxytocin infusion)
Method of measurement
based on test

2

Description
need to extra uterotonic drug
Timepoint
after cesarean (after oxytocin infusion)
Method of measurement
based on diagnostic test

3

Description
systolic blood pressure (under 100 mm Hg)
Timepoint
after cesarean (after oxytocin infusion)
Method of measurement
based on test

Intervention groups

1

Description
oxytocin dose (30 and 80 UST unit in 500cc Ringer serum respectively for group one and two)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam-o-Al-Anbia hospital
Full name of responsible person
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2

Recruitment center
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Sponsors / Funding sources

1

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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
Medical School, Zahedan University of Medical sciences
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

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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