

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 hemorrhage 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 uterotonic drug need while and after surgery (0 as compared with 22.6% and Pvalue=0) ; whereas, there were no significant difference between control and 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 uterotonic 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

Name

Fatameh Ahmadi

Name of organization / entity

Zahedan University of Medical sciences, Medical School

Country

Iran (Islamic Republic of)

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+98 54 3329 5831

Email address

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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

Zahedan

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

Fatameh Ahmadi

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2

Recruitment center

Name of recruitment center

Imam Ali hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical School, Zahedan University of Medical sciences

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

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

Contact

Name of organization / entity

Zahedan University of Medical sciences

Full name of responsible person

Fatameh Ahmadi

Position

resident of Gynecology and Obstetrics

Other areas of specialty/work

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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