Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Sublingual misoprostol to reduce blood loss at cesarean delivery

Protocol summary

Summary

This randomized clinical trial will be conducted in 1395 on 90 term pregnant women with risk factor for postpartum hemorrhage in Omolbanin hospital, Mashhad with spinal anesthesia. Patients will be assigned randomly (with random block method) in to two groups (intervention group: 30 unite intravenous oxytocin in 1000 cc ringer infusion [10ml/m] in 30 minutes and then 2 ml/min for next 6 hours plus 400 microgram sublingual misoprostol after cord clamping, control group: intervention group: 30 unite intravenous oxytocin in 1000 cc ringer infusion [10ml/m] in 30 minutes and then 2 ml/min for next 6 hours). Hemorrhage rate would be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030126857N1**
Registration date: **2017-01-18, 1395/10/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name
Roya Jalali
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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jalalir921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sublingual misoprostol to reduce blood loss at cesarean delivery

Public title

Sublingual misoprostol to reduce blood loss at cesarean delivery

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: the term pregnant women with risk factor for post partum hemorrhage such as uterine overdistention (multifetal gestatation.macrosomia), arrest disorder, prolonged induction and prolonged preterm rupture of membrane exclusion criteria: Lack of consent, coagulation disorders , Anemia, Intraabdominal adhesion, Intraoperative bladder and intestines and other viscera damage, Abnormal adhesion of placenta, extended Uterine incision during cesarean delivery and known hypersensitivity to misoprostol.

Age

No age limit

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will be assigned randomly (with random block method) in to two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Administration Center(Qoreishi Building) – Daneshgah St. – Mashhad – Iran

City

Mashhad

Postal code

Approval date

2016-01-05, 1394/10/15

Ethics committee reference number

IR.MUMS.fm.REC.1394.354

Health conditions studied

1

Description of health condition studied

postpartum hemorrhage

ICD-10 code

072

ICD-10 code description

Haemorrhage after delivery of fetus or infant

Primary outcomes

1

Description

Mean estimate blood loss

Timepoint

During surgery

Method of measurement

Milliliter

Secondary outcomes

1

Description

Adverse effect

Timepoint

In the first day after surgery

Method of measurement

presence or absence

Intervention groups

1

Description

intervention group: 30 unite intravenous oxytocin in 1000 cc ringer infusion [10ml/m] in 30 minutes and then 2 ml/min for next 6 hours plus 400 microgram sublingual misoprostol after cord clamping

Category

Treatment - Drugs

2

Description

control group: intervention group: 30 unite intravenous oxytocin in 1000 cc ringer infusion [10ml/m] in 30 minutes and then 2 ml/min for next 6 hours

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin hospital

Full name of responsible person

Dr. Roya Jalali

Street address

Mashhad University of Medical Sciences

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research of mashhad university of medical science

Full name of responsible person

Dr. Saied Eslami

Street address

Mashhad University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice President of Research of mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Roya Jalali

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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Name of organization / entity

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Resident of Obstetrics and Gynecology

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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