

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigating the incidence of postpartum hemorrhage in high-risk pregnant women who underwent cesarean section after the prophylactic administration of misoprostol, metrogen, and oxytocin compared to oxytocin alone

Protocol summary

Study aim

Investigating the incidence of postpartum hemorrhage in high-risk pregnant women who underwent cesarean section after the prophylactic administration of misoprostol, metrogen, and oxytocin compared to oxytocin alone

Design

This three-phase, with parallel groups, single-blind clinical trial is performed on 240 pregnant women. The participants are allocated to the intervention groups using the allocation randomization rule.

Settings and conduct

In this interventional study, 240 pregnant women in Yas Hospital are selected by convenience sampling. Then, using the randomization method, 160 women are placed in intervention groups (oxytocin + misoprostol or oxytocin + metrogen) and 80 women are placed in the control group (oxytocin). This study is single-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: singleton-term pregnant women who have an indication for an elective cesarean section with at least one risk factor for postpartum bleeding.

Exclusion criteria: abnormalities in the mother, the fetus or the placenta.

Intervention groups

In all participants, an intravenous infusion of 40 units of oxytocin in 1 liter of Ringer's serum (10 ccs per minute for 30 minutes) is done and then continued at 2 ccs per minute for one hour. In intervention group A, after clamping the umbilical cord, 400 micrograms of misoprostol and in intervention group B, an ampoule of metrogen (0.2 mg) is prescribed. The control group receives only oxytocin.

Main outcome variables

Incidence of postpartum hemorrhage: Hemoglobin and hematocrit concentration six hours after the cesarean

section.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230227057554N1**

Registration date: **2023-03-18, 1401/12/27**

Registration timing: **prospective**

Last update: **2023-03-18, 1401/12/27**

Update count: **0**

Registration date

2023-03-18, 1401/12/27

Registrant information

Name

Mahboobeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4216 0852

Email address

mahboobehshirazi4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the incidence of postpartum hemorrhage in high-risk pregnant women who underwent cesarean section after the prophylactic administration of misoprostol, metronen, and oxytocin compared to oxytocin alone

Public title

The effect of misoprostol, and metronen with oxytocin in reducing of postpartum hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Singleton term pregnant women who have an indication for termination of pregnancy (37-40 weeks). Have an indication for an elective cesarean section. At least one risk factor for postpartum bleeding (such as polyhydramnios, multiparity, having a history of postpartum bleeding, macrosomia, and anemia).

Exclusion criteria:

Emergency cesarean section Abnormal fetal heartbeat Vaginal bleeding Person with unexpected bleeding during the surgery Severe anemia (hemoglobin less than 8 mg/dL) before surgery Advanced underlying diseases History of coagulation disorders Low-lying placenta, decolman or accreta previa Reaction history to the drugs

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random allocation rule, people are placed in one of the study groups (intervention group A (misoprostol + oxytocin), intervention group B (metronen + oxytocin), and control group C (oxytocin)). First, 80 letters A, 80 letters B, and 80 letters C are written on special papers that are not marked inside. Then all of them (240 pieces) are placed in a bag and for each patient, after obtaining informed consent, a piece of paper is randomly removed without replacement, and based on the letter written on it, the desired intervention is performed for the patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient and the anesthesiologist know about the group assignment process, but the person gathering

data (gynecological resident) does not know about the grouping of patients. Therefore, the study is single-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina Ave., Qods Blvd.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2023-01-11, 1401/10/21

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.763

Health conditions studied**1****Description of health condition studied**

Postpartum hemorrhage

ICD-10 code

O72

ICD-10 code description

Postpartum hemorrhage

Primary outcomes**1****Description**

Incidence of postpartum hemorrhage

Timepoint

Once, six hours after the caesarean section

Method of measurement

Number of pads used in the first six hours after the caesarean section

Secondary outcomes

1

Description

Hemoglobin and hematocrit concentration

Timepoint

Once, six hours after the cesarean section

Method of measurement

Complete blood count

Intervention groups

1

Description

Intervention group: In these women, the intravenous infusion of 40 units of oxytocin (produced by Aburaihan Pharmaceutical Manufacturing) in 1 liter of Ringer's serum at a rate of 10 ccs per minute for 30 minutes is done and then continued at 2 ccs per minute for one hour. After clamping the umbilical cord 400 micrograms of misoprostol (produced by Samisaz Pharmaceutical Manufacturing) is placed in the patient's sublingual space by the anesthesia technician.

Category

Prevention

2

Description

Intervention group: In these women, the intravenous infusion of 40 units of oxytocin (produced by Aburaihan Pharmaceutical Manufacturing) in 1 liter of Ringer's serum at a rate of 10 ccs per minute for 30 minutes is done and then continued at 2 ccs per minute for one hour. After clamping the umbilical cord, an ampoule of metrogel (0.2 mg), produced by Minoo Pharmaceutical Manufacturing, is injected into the patient by the anesthesia technician.

Category

Prevention

3

Description

Control group: In these women, the intravenous infusion of 40 units of oxytocin (produced by Aburaihan Pharmaceutical Manufacturing) in 1 liter of Ringer's serum at a rate of 10 ccs per minute for 30 minutes is done and then continued at 2 ccs per minute for one hour.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Mahboobeh Shirazi

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Yas Hospital, Ostad Nejatollahi Ave., Karimkhan Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi

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Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahboobeh Shirazi

Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified participants.

When the data will become available and for how long

After the manuscript is published.

To whom data/document is available

No limitations.

Under which criteria data/document could be used

Those who are allowed to request to receive nonidentifiable personal data or other documents must have a written proposal (including the type of statistical analysis) and the ethics number. any additional analysis must perform under the corresponding author's supervision.

From where data/document is obtainable

Communicate with the corresponding author via email: mahboobehshirazi4@gmail.com

What processes are involved for a request to access data/document

Any request must be sent through e-mail and accompanied by a proposal with an ethics code under the supervision of Dr. Shirazi.

Comments