Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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, metrogen, and oxytocin compared to oxytocin alone

Public title
The effect of misoprostol, and metrogen 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 (metrogen + 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
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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 metrogen (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 Nejatolahi Ave., Karimkhan Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi
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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
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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