Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the effects of misoprostol and oxytocine on postpartum Hemorrhage

Protocol summary

Study aim
Comparison of postpartum hemorrhage in three groups receiving oxytocin, sublingual misoprostol and intrauterine misoprostol

Design
Clinical trial without control group, with parallel groups, double-blind, randomized, phase 2 on 237 patients. Excel software rand function was used for randomization.

Settings and conduct
Sequences of the intervention groups will be provided for the operating room in matte envelopes, and When the cesarean section is started, it will be opened by the nurse cooperating in the study. All participants and surgeons will be unaware of the grouping of the participants before the time of the intervention. Intervention will be applied in the operating room after placental abruption to all three groups

Participants/Inclusion and exclusion criteria
Pregnant women between the ages of 18 and 40 with a term pregnancy will be included in the study if they have a history of cesarean section and will be excluded from the study if they have coagulation problems and multiple pregnancies.

Intervention groups
Intervention group 1: Oxytocin 10 units (inside 500 cc of Ringer serum) and sublingual misoprostol tablets of 400 micrograms (after placental abruption and uterine correction are inserted in the patient's sublingual and controlled by anesthesia technician to prevent suffocation) Intervention group 2: Oxytocin recipient 10 units (inside 500 cc of Ringer serum) and intrauterine misoprostol tablet of 400 micrograms (after placental abruption and uterine correction, it is inserted in two uterine poles - 200 micrograms in each cornea) Intervention group 3: Oxytocin receptor 30 units (within 500 cc of Ringer serum)

Main outcome variables
Bleeding volume during cesarean section and within 24 hours after surgery; Drug side effects and duration of surgery

General information

Reason for update
Confirmation of the registration date of the randomized clinical trial in the Iranian Clinical Trials Registry (IRCT) and the date of registration of the first patient.

Acronym

IRCT registration information
IRCT registration number: **IRCT20100429003833N2**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**
Update count: **1**

Registration date
2021-10-02, 1400/07/10

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
3373741
Email address
rahmaniv@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of misoprostol and oxytocine on postpartum Hemorrhage

Public title

Comparison of the effects of misoprostol and oxytocine on postpartum Hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

singleton pregnant women elective cesarean delivery Maximum history of once cesarean section

Exclusion criteria:

Preeclampsia Cardiovascular diseases Uterine myoma A history of excessive bleeding after delivery. Underlying disease, such as coagulopathy Abnormal placental implantation (Placenta peria or Ecrta)

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **237**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be divided into three groups using a table of random numbers. This table contains the numbers 1 to 237 irregularly and without a specific pattern. To prepare this table, the site https://www.Randomization.com will be used. Numbers will be read by default (up, down, left or right). Then, the numbers 0-90 will be considered for group A, the numbers 91-181 for group B and the numbers 182-273 for group C. For concealment, opaque and sealed envelopes will be used. Each number will be written on a card and the cards will be placed inside the envelopes. When a patient enters the study, one of the envelopes is opened and the assigned group of that patient is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Sequences of the intervention groups will be provided for the operating room in matte envelopes, and When the cesarean section is started, it will be opened by the nurse cooperating in the study. Each group will be treated according to a specific treatment protocol. All participants and surgeons will be unaware of the grouping of the participants before the time of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.409

Health conditions studied

1

Description of health condition studied

Postpartum hemorrhage

ICD-10 code

072.1

ICD-10 code description

Other immediate postpartum haemorrhage

Primary outcomes

1

Description

Bleeding volume during cesarean section

Timepoint

After the placenta is removed until the uterus is repaired

Method of measurement

Number of gases and lumps of wet gases and volume of blood in suction

2

Description

Bleeding volume during the first 24 hours of cesarean section

Timepoint

Hemoglobin and hematocrit are measured 24 hours after surgery and compared with preoperative values.

Method of measurement

blood test

3

Description

Duration of surgery

Timepoint

From the start of surgery to complete repair of the uterus

Method of measurement

Record start and end times

Secondary outcomes

1

Description

Drug side effects

Timepoint

From the time of hospitalization to the patient's discharge

Method of measurement

Control vital signs

Intervention groups

1

Description

Intervention group 1: Oxytocin 10 units (inside 500 cc of Ringer's serum) and sublingual misoprostol tablets of 400 micrograms (after placental abruption and uterine correction are inserted in the patient's sublingual and controlled by anesthesia technician to prevent suffocation.)

Category

Treatment - Drugs

2

Description

Intervention group 2: Oxytocin recipient 10 units (inside 500 cc of Ringer serum) and intrauterine misoprostol tablet of 400 micrograms (after placental abruption and uterine correction, it is inserted in two uterine poles - 200 micrograms in each cornea)

Category

Treatment - Drugs

3

Description

Intervention group 3: Oxytocin receptor 30 units (within 500 cc of Ringer serum)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Vahideh Rahmani

Street address

Alzahra Hospital, South Artesh St.,Tabriz, iran

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Province

East Azarbaijan

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5138665793

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+98 41 3553 9161

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lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Mohammad Samiei

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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lahroudin@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Vahideh Rahmani

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available