Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of sublingual mesoprostol, rectal and venous oxytocin on cesarean uterine bleeding

Protocol summary

Study aim
Comparison of the effect of sublingual mesoprostol, rectal and venous oxytocin on cesarean uterine bleeding

Design
Clinical trial with control group, with parallel groups, single blind, simple random,Randomization through block randomization, on 180 patients.

Settings and conduct
This study will be performed on a single blind in the operating room of Shahid Sayad Shirazi Hospital in Gorgan on pregnant mothers who are candidates for cesarean section. The sampling method is random and through block randomization, the samples are divided into 3 groups of 60 people. We divide: (groups A, B and C) 1) Group A: Sublingual mesoprostol tablets + intravenous oxytocin 2) Group B: Rectal misoprostol tablets + intravenous oxytocin 3) Group C = or control : Intravenous oxytocin

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients between the ages of 18 and 40, cesarean section candidate, gestational age between 37 and 40 weeks, Spinal anesthesia candidate, patient consent, single pregnancy and low transverse uterine incision. Exclusion criteria: history of PPH (postpartum hemorrhage), placenta proia and acarta, liver or kidney disease, eclampsia and preeclampsia, epilepsy, height below 155 cm, obesity (BMI> 40) (BMI = Body mass index), infant weight over 4 kg, polyhydramnios (increase) Amniotic fluid), patients receiving anticoagulants, patients with heart and lung problems and underlying diseases such as diabetes, hypertension (hypertension above 140/90 mm Hg), chronic anemia, coagulation disorders and immunodeficiency.

Intervention groups
Samples will be divided into three groups, A, B and C. 1) Group A: Sublingual mesoprostol tablets + intravenous oxytocin 2) Group B: Rectal misoprostol tablets + intravenous oxytocin 3) Group C = or control : Intravenous oxytocin

Main outcome variables
Bleeding during cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200501047257N1**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-18, 1399/02/29**
Update count: **0**

Registration date
2020-05-18, 1399/02/29

Registrant information

Name
Fatemeh Zahra Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 17 3223 3381

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-10, 1399/02/21

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of sublingual mesoprostol, rectal and venous oxytocin on cesarean uterine bleeding

Public title
Evaluation of the effect of misoprostol on cesarean bleeding

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients between the ages of 18 and 40 Candidates for cesarean section Gestational age between 37 and 40 weeks Candidates for Spinal anesthesia Written consent from the patient Single pregnancy Low transverse uterine incision

Exclusion criteria:
History of PPH (postpartum hemorrhage) Placenta previa and acarta Liver or kidney disease Eclampsia and preeclampsia Epilepsy Height below 155 cm Obesity (BMI> 40) (BMI = Body mass index) Infant weight over 4 kg Polyhydramnios (increased amniotic fluid) Patients received Anti-coagulation drugs Patients with heart and lung problems and underlying diseases such as diabetes, high blood pressure (140/90 mm Hg), chronic anemia, coagulation disorders and immunodeficiency

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

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate groups via permutation block randomization will be used, patients in the study using the blocks 6 each using the letters A, B, and C (for equality groups), the patients into 3 groups of 6 people divided . For permutation block randomization method of sealed envelopes with random sequences will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blindness is performed for statistical counselors as statistical counselors are not aware of the type of data they perform for analysis and only the data are identified by three groups A, B and C, and they are named by groups. And the method of intervention is unknown.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Sari, Farahabad Road, Mazandaran University of Medical Sciences, School of Paramedical Sciences

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2020-04-29, 1399/02/10

Ethics committee reference number
IR.MAZUMS.REC.1399.134

Health conditions studied

1

Description of health condition studied
The amount of bleeding from a cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Bleeding during cesarean section

Timepoint
Bleeding is removed during surgery and after surgery

Method of measurement
The amount of blood lost in each group at the end of the operation, based on the amount of blood in the suction and the estimated blood volume absorbed by each gauze and long gauze with the scales before and after The operation is weighed and the amount of clot excreted from the vagina after uterine massage is calculated at the end of the operation and will be recorded in the desired checklist.

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: After umbilical cord clamping during surgery, the patient will receive 20 oxytocin units within half a liter of Ringer's serum at a rate of 15 cc per minute.In the first intervention group, we place 200 micrograms of misoprostol in the patient's sublingual (It should be noted that Mizoprostol 100 mg tablets are from Abu Reihan Company and 10 units of Oxytocin ampoules are from Alborz Daroo Company). If proper uterine contraction does not occur after a few minutes (maximum 5 minutes), if the initial intervention is not enough, oxytocin will be repeated up to 100 units (inside the Ringer's serum) and if we need more medication, misoprostol. We continue up to 1000 micrograms

Category
Treatment - Surgery

2

Description
Second intervention group: After umbilical cord clamping during surgery, the patient will receive 20 oxytocin units within half a liter of Ringer's serum at a rate of 15 cc per minute.In the second intervention group, we place 200 micrograms of misoprostol in the patient's rectal area (It should be noted that Mizoprostol 100 mg tablets are from Abu Reihan Company and 10 units of Oxytocin ampoules are from Alborz Daroo Company). If proper uterine contraction does not occur after a few minutes (maximum 5 minutes), if the initial intervention is not enough, oxytocin will be repeated up to 100 units (inside the Ringer's serum) and if we need more medication, misoprostol. We continue up to 1000 micrograms

Category
Treatment - Surgery

3

Description
Control group: After umbilical cord clamping during surgery, the patient will receive 20 oxytocin units within half a liter of Ringer's serum at a rate of 15 cc per minute(It should be noted that the oxytocin ampoule is 10 units from Alborz Daroo Co.) . If proper uterine contraction does not occur after a few minutes (maximum 5 minutes), oxytocin is repeated for up to 100 units (inside the Ringer's serum).

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sayad Shirazi Hospital

Full name of responsible person
Mahboobeh Azadeh Rah

Street address
Shahid Sayad Shirazi Blvd., Shahid Sayad Shirazi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Majid Saeedi

Street address
Sari, Imam Square, Joibar Three Ways, at the beginning of Valiasr Highway, Central Headquarters of Mazandaran University of Medical Sciences

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Sari

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Mazandaran

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4815733971

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magsaeedi@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Fatemeh Zahra Bagheri

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Surgical technology

Street address

Gorgan Jadid First Street, 1st Alley, in front of Rosta Complex, two-storey private house

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Person responsible for scientific inquiries

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Hooshang Akbari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Zahra Bagheri

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

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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