Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Determination of the effect of vaginal misoprostol on post myomectomy bleeding: A double-blind randomized clinical trial

Protocol summary

Study aim
Determination and comparison of bleeding after myomectomy in patients receiving misoprostol and placebo control group

Design
The samples are randomly assigned to one of the two intervention and control groups using the software. In this way, all possible four blocks that include two groups are written and each number is assigned to one of the blocks in the table. Based on the table of random numbers obtained by a computer program, a block is selected and based on that, the samples entered into the study will be entered into different groups. A total of 34 samples were determined in each group (a total of 68 samples).

Settings and conduct
Individuals will be randomly assigned to computer groups one and two. People in group one will receive a dose of 200 micrograms of vaginal misoprostol (before surgery in the operating room before the patient's forehead) and the control group will receive B6 tablets vaginally. The surgical procedure for all patients includes the standard standard open myomectomy surgery performed by a physician at Sayad Shirazi Hospital. And the amount of bleeding during the operation is measured based on accurate suction, gas and lameness.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years Myoma less than 8 cm in size on ultrasound Married Exclusion criteria: Contraindications to misoprostol Hemorrhagic disease Active asthma High diastolic blood pressure Recent use of nonsteroidal anti-inflammatory drugs History of severe anemia; Allergies and recent blood transfusions

Intervention groups
The intervention group, who will receive a dose of 200 micrograms of vaginal misoprostol (before surgery in the operating room) Control group: The control group will receive B6 pills vaginally.

Main outcome variables
Bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220101053581N1**
Registration date: **2022-05-21, 1401/02/31**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-21, 1401/02/31**
Update count: **0**

Registration date
2022-05-21, 1401/02/31

Registrant information

Name
maryam mazji

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3523 2001

Email address
m_mazji@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-07-11, 1401/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Determination of the effect of vaginal misoprostol on post myomectomy bleeding: A double-blind randomized clinical trial

Public title
Survey of the effect of vaginal misoprostol on post myomectomy bleeding

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Myoma less than 8 cm in size on ultrasound married

Exclusion criteria:
Contraindications to misoprostol Hemorrhagic disease Active asthma High diastolic blood pressure Recent use of nonsteroidal anti-inflammatory drugs History of severe anemia; Allergies and recent blood transfusions

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples were divided into control and intervention groups based on random allocation of quadruple blockade. For this purpose, the four blocks were selected so that the intervention group had the letter A and the control group the letter B. 6 possible modes were written on separate cards and each card was assigned a number from one to six. The numbers were then written on paper and removed randomly. Until the expected number of samples was completed. In this study, the online randomization service (http // www.sealedenvelope.com / simple-randomiser / v1 / lists) was used to block block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Sequence concealment was performed using packets in packages. In this way, one of the letters was placed inside each envelope in the specified order and then the lid of the envelope was closed and given to the researcher. The use of random allocation largely controlled the confounding variables, but the research team also included potential confounding variables in the designed questionnaire and analyzed their effect. The researcher will also be unaware of the assignment of individuals in groups due to hiding the sequence of individuals in groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Sayad Shirazi Street, Sayad Shirazi Hospital

City
GORGAN

Province
Golestan

Postal code
74394917867

Approval date
2021-12-04, 1400/09/13

Ethics committee reference number
IR.GOUMS.REC.1400.322

Health conditions studied

1

Description of health condition studied
Uterine myoma

ICD-10 code
D25.9

ICD-10 code description
Leiomyoma of uterus, unspecified

Primary outcomes

1

Description
Reduce vaginal bleeding

Timepoint
During surgery and 6 hours after surgery

Method of measurement
Based on suction and gas and long gas

Secondary outcomes

1

Description
Decreased transfusion of blood products

Timepoint
6 hours after surgery

Method of measurement
Measurement of hemoglobin

Intervention groups

1

Description
After obtaining permission from the authorities and explanations about the method of intervention to patients and completing the form of demographic questionnaire, patients will be randomly divided into two groups of control and intervention. On the day of surgery before the start of the patient's surgery (in the patient preparation phase), patients with the intervention group will be administered 200 micrograms of misoprostol vaginally. Bleeding during the operation will then be estimated by the amount of gas and blood clot and suction.
Category
Treatment - Surgery

2

Description
patients in the control group, placebo (tablet B6) will be used vaginally before surgery and the amount of bleeding during the operation will be measured by measuring gas and blood clots and suction.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sayad Shirazi Hospital, Gorgan
Full name of responsible person
Maryam Mazji
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Sayad Shirazi Hospital, Gorgan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
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Street address
Gorgan Kordkoy Road, Philosophy Educational Complex, Vice Chancellor for Research and Technology
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Web page address
https://goums.ac.ir/index.php?slc_lang=fa&sid=12
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Maryam Mazji
Position
The Rezident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Position

REZIDENT

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

Part of the main outcome data includes personal information and the main outcome results

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

researchers

Under which criteria data/document could be used

Only researchers to conduct similar studies

From where data/document is obtainable

Dr. Maryam Mazji Email: m_mazji@yahoo.com

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

Correspond with the researcher via email

Comments