Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Effect of rectal Misoprostol in reducing blood loss before hysterectomy and myomectomy

Protocol summary

Study aim
Determining the effect of rectal misoprostol on reducing blood loss before hysterectomy and myomectomy

Design
Clinical trial with community-based and pragmatic control group, with parallel groups, double-blind, randomized

Settings and conduct
This double-blind clinical trial is performed on candidates for total hysterectomy with and without bilateral salpingo-ovariectomy and myomectomy due to symptomatic uterine fibromas that are admitted to the surgical ward of the Ayatullah Rohani hospital in Babol in 2017.

Participants/Inclusion and exclusion criteria
Age between 35 and 50 years, The number of uterine fibroids is 5 or less, The maximum size of the largest fiber is 3 cm, all fibroids are subserosa or intramural in ultrasound, Uterus size in two-handed examination is less than 24 weeks pregnancy if need for myomectomy, Exclusion criteria: Any contraindication for using Misoprostol, The presence of malignancy, History of previous laparotomy except cesarean section, History of endometriosis, Cardiovascular and pulmonary diseases, Bleeding disorders, Hemoglobin below 10 g / dl, Body mass index greater than 30 kg / m², Previous Myomectomy history, History of using misoprostol with GnRH immediately before surgery, Unwillingness to enter the study.

Intervention groups
The first group will receive 400 micrograms misoprostol (200 µg P.I.C High Wycombe, England) and the second group will receive placebo, rectally 30 minutes before surgery.

Main outcome variables
bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181020041394N1**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date
2018-11-30, 1397/09/09

Registrant information

Name
Azita Ghanbarpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-13, 1397/03/23

Expected recruitment end date
2019-06-13, 1398/03/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of rectal Misoprostol in reducing blood loss before hysterectomy and myomectomy

Public title
Effect of rectal Misoprostol in reducing blood loss before hysterectomy and myomectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 35 and 50 years The number of uterine fibroids is 5 or less The maximum size of the largest fiber is 3 cm All fibromas are subserosal or intramural in ultrasound Uterus size less than 24 weeks pregnant with two-handed examination if need for myomectomy

Exclusion criteria:
Any contraindication for using Misoprostol The presence of malignancy History of previous laparotomy except cesarean section History of endometriosis Cardiovascular and pulmonary diseases Bleeding disorders Hemoglobin below 10 g / dl Body mass index greater than 30 kg / m² Previous Myomectomy History History of using misoprostol with GnRH immediately before surgery Unwillingness to enter the study

Age
From **35 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be divided into two groups by a simple random method. In this research, the coin toss will be used to create a random sequence in a two-group trial. So that one of the study groups is tail and the other group is considered as a head, and according to the sample size, the same amount of coin is tossed and the subjects are divided into two groups of random allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
All patients, nurses and researcher are blind in this study, and drug therapy is based on codes only by the head nurse of the gynecology department.

Placebo
Used

Assignment
Parallel

Other design features
.

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Ganj Afrouz Avenue, Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
478956-1

Approval date
2018-05-13, 1397/02/23

Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.114

Health conditions studied

1

Description of health condition studied
Uterine lymphoma

ICD-10 code
D25

ICD-10 code description
benign neoplasms of uterus with morphology code M889 and behaviour code /0 fibromyoma of uterus

Primary outcomes

1

Description
Amount of bleeding during surgery

Timepoint
After the end of the surgery

Method of measurement
Volume of available hemorrhage in the suction device and the counting and calculation of blood gases

2

Description
Postoperative hemoglobin loss

Timepoint
Before surgery and 6 hours after surgery

Method of measurement
In grams per dL of the blood sample before surgery and 6 hours after surgery

Secondary outcomes

1

Description
Complications after surgery
Timepoint
From the time of transfer to the department up to two weeks after the operation
Method of measurement
The incidence of complications is noted

2

Description
The incidence of complications during surgery
Timepoint
During surgery
Method of measurement
The incidence of complications is noted

3

Description
Length of the surgery
Timepoint
During surgery
Method of measurement
From the time of the initial entry of the laparoscopic tooth skinning to the skin in minutes

4

Description
Hemodynamic changes during surgery
Timepoint
During surgery
Method of measurement
The mean of vital signs registered during anesthesia by anesthesiologist is in mm of mercury (blood pressure), beats per minute (heart rate), centimeters (body temperature)

Intervention groups

1

Description
Intervention group: The first group received 400 micrograms of rectal misoprostol (200 micrograms, P.I.C., High Wycombe, England) 30 minutes before surgery.
Category
Treatment - Drugs

2

Description
Control group: The second group received rectal placebo 30 minutes before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Ayatullah Rouhani Babol
Full name of responsible person
Dr. Azita Ghanbarpour
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Ayatullah Rouhani Hospital in Babol, Ganj Afrooz Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Dr. Azita Ghanbarpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
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Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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