

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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)

Phone

+98 11 3219 9592

Email address

a.ghanbarpour@mubabol.ac.ir

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

Street address

Ayatullah Rouhani Hospital in Babol, Ganj Afrooz Avenue

City

Babol

Province

Mazandaran

Postal code

147896-1

Phone

+98 11 3225 6285

Email

a.ghanbarpour@mubabol.ac.ir

Web page address

<http://www.mubabol.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Babol University of Medical Sciences, Ganj Afrooz Avenue

City

Babol

Province

Mazandaran

Postal code

147896-1

Phone

+98 11 3225 6285

Email

rezaghadimi@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

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

Street address

Babol University of Medical Sciences, Ganj Afrouz Avenue

City

Babol

Province

Mazandaran

Postal code

147896-1

Phone

+98 11 3225 6285

Email

a.ghanbarpour@mubabol.ac.ir

Web page address

<http://www.mubabol.ac.ir/>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr. Maedeh Molla Alipour

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Babol University of Medical Sciences, Ganj Afrouz Avenue

City

Babol

Province

Mazandaran

Postal code

147896-1

Phone

+98 11 3222 7667

Email

neda_amani69@yahoo.com

Web page address

<http://www.mubabol.ac.ir/>

Person responsible for updating data**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

Street address

Babol University of Medical Sciences, Ganj Afrouz Avenue

City

Babol

Province

Mazandaran

Postal code

147896-1

Phone

+98 11 3225 6285

Email

a.ghanbarpour@mubabol.ac.ir

Web page address

<http://www.mubabol.ac.ir/>

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**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