

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Evaluating the effects of rectal misoprostol prior to myomectomy on the volume of hemorrhage in versus of placebo in al Zahra hospital patients with intramural myoma from 2017-2018

Protocol summary

Study aim

Evaluating the effect of preoperative rectal misoprostol administration on the volume of hemorrhage during and after myomectomy operation in patients with symptomatic intermural myoma admitted to Alzahra Dasal Hospital in 2017-2018

Design

A randomized, double blind clinical trial with parallel control and intervention groups was performed on 94 patients with myoma.

Settings and conduct

In this randomized clinical trial, patients referred to the Al-Zahra Educational Hospital during the years 2017-2018, which are referred to as symptomatic myomas, are evaluated. The operator fills in the encoded form (including demographic characteristics and delivery history according to medical records). The patient and the outcome evaluator of pain (second operator) do not know the nature of the codes (double blind study).

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Women 18 to 50 years old, 5 or less symptomatic myoma, intramural myoma based on sonography, A minimum of 4 cm in size of myoma. Exclusion criteria: anemia (HB less than 10), allergy to Misoprostol, Cardiopulmonary diseases, Hemorrhage disorders, Body mass index more than 35, Uncontrolled blood pressure despite drug use, uterine size more than 24 weeks

Intervention groups

Before starting the operation, in the control group, placebo and in the intervention group, misoprostol 400 micrograms of rectal dosage was prescribed. Then its effect on bleeding during the operation and the level of hemoglobin 4 and 24 hours after surgery are compared.

Main outcome variables

the volume of hemorrhage during and after myomectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080826001096N5**

Registration date: **2018-04-26, 1397/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-26, 1397/02/06**

Update count: **0**

Registration date

2018-04-26, 1397/02/06

Registrant information

Name

Seyede Hajar Sharami

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	The participants in the study and the person who evaluated the outcome of the pain (second operator) do not know the nature of the codes (double blind study).
Scientific title Evaluating the effects of rectal misoprostol prior to myomectomy on the volume of hemorrhage in versus of placebo in al Zahra hospital patients with intramural myoma from 2017-2018	Placebo Used
Public title rectal misoprostol on intraoperative blood loss prior to abdominal myomectomy.	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: age between 18-50 years 5 or less symptomatic myoma intramoral myoma based on sonography A minimum of 4 cm in size of myoma (because no smaller than 4 cm can produce a lot of bleeding) Exclusion criteria: anemia (HB less than10) allergy to Misoprostol (By asking questions such as skin sign, hives, rash, shortness of breath, coughing, chest pain after the previous use of Miso Prostol) Cardiopulmonary diseases Hemorrhage disorders obese (Body Mass Index more than35) Uncontrolled blood pressure despite drug use uterine size more than 24 weeks	Secondary Ids empty
Age From 18 years old to 50 years old	Ethics committees <u>1</u>
Gender Female	Ethics committee Name of ethics committee • Ethics committee of Guilan University of Medical Sciences
Phase 3	Street address Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN
Groups that have been masked • Participant • Care provider	City Rasht
Sample size Target sample size: 94	Province Guilan
Randomization (investigator's opinion) Randomized	Postal code 41446-66949
Randomization description A randomized random blocking technique in one of the 4 blocks (aabb, abab, baba, bbaa) is divided into two groups receiving placebo, receiving misoprostol, by Skilled trained technician. The hemoglobin is measured and recorded before surgery in the laboratory. To be blinded, Misoprostol (Miso Glendine, Sami Mus) with a dose of 400 micrograms of rectal one hour before surgery by the head nurse of the electrocardiogram section, the midwife of the collaborator, who is not a research team, is placed in the patient. In the control group, a placebo tablet of the shape and size They are similar to misoprostol but contain inert material. All collected data is documented and recorded in hospital records. All surgical procedures are performed by the Fanstile cut.Numerical comparison and filling out all of the above information, separately and Double blind, are carried out by two gynecologic assistants.	Approval date 2017-09-23, 1396/07/01
Blinding (investigator's opinion) Double blinded	Ethics committee reference number IR.GUMS.REC.1396.257
Blinding description	Health conditions studied <u>1</u> Description of health condition studied myoma ICD-10 code D25 ICD-10 code description Leiomyoma of uterus
	Primary outcomes <u>1</u> Description Length of stay in hospital Timepoint From admission to exit Method of measurement day
	Secondary outcomes

1

Description

Postoperative hemoglobin and hematocrit

Timepoint

4 and 24 hours after surgery

Method of measurement

blood test

2

Description

blood loss

Timepoint

Intraoperative and postoperative

Method of measurement

On hemoglobin level and Severity of bleeding Total blood volume in the suction bottle + wet gauze and long gauze

Intervention groups

1

Description

Intervention group: 2 pills equal to 400 mcg misoprostol will be placed rectal one hour before the surgery.

Category

Treatment - Drugs

2

Description

Control group: 2 pills vitamin B6 will be placed rectal one hour before the surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr.Seyedeh Hajar Sharami

Street address

Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Research vice-chancellorship

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Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN

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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

Guilan 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

Guilan university of Medical Sciences

Full name of responsible person

Fatemeh Hosseini

Position

Resident of Professor, Guilan university of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

There is still planning to share and publish.

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the study results.

To whom data/document is available

All interested in study.

Under which criteria data/document could be used

En Not yet planned for it.

From where data/document is obtainable

sharami@gums.ac.ir

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

Not yet planned for it.

Comments