Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 interimural 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, intramoral myoma based on sonography, A minimum of 4 cm in size of myoma. Exclusion criteria:anemia (HB less than10),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

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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

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

Public title

rectal misoprostol on intraoperative blood loss prior to abdominal myomectomy.

Purpose

Treatment

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

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Double blinded

Blinding description

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).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

• Ethics committee of Guilan University of Medical Sciences

Street address

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

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.GUMS.REC.1396.257

Health conditions studied

1

Description of health condition studied

myoma

ICD-10 code

D25

ICD-10 code description

Leiomyoma of uterus

Primary outcomes

1

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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