

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of a single dose of sublingual misoprostol on blood loss in total abdominal hysterectomy in patients with uterine myoma

Protocol summary

Summary

This randomized Double-blind clinical trial study will be conducted after approval from the ethics committee of Mashhad University of Medical Sciences during 2016 to 2017. Study group consists of 100 women who will be undergoing abdominal hysterectomy with or without removal of the ovaries due to uterine myoma and meets inclusion criteria. They will be randomly divided into two groups (study and control groups). Study and control group will receive a misoprostol pack (400µg) or a pack of Placebo before operation, respectively. The placebo pack is completely similar to misoprostol and will be prepared by pharmacologist and applied sublingually for the patient half hours before operation. Random allocation is done by methodologist, and results of the project will be sealed in envelopes. No one knows about the allocation for the confidentiality of the patients data. Gravimetric methods (The gravity of bloody sponges, The amount of blood inside the suction device) will be used to estimate the amount of bleeding during surgery and The hemoglobin level will be measured 24 hours after surgery.

General information

Acronym

TAH

IRCT registration information

IRCT registration number: **IRCT2016122831635N1**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-09, 1396/03/19

Registrant information

Name

Salme Dadgar

Name of organization / entity

Mashhad university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

dadgars@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences.

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-04-04, 1397/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a single dose of sublingual misoprostol on blood loss in total abdominal hysterectomy in patients with uterine myoma

Public title

The effect of a single dose of sublingual misoprostol on blood loss in total abdominal hysterectomy in patients with uterine myoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who choose to be treated by TAH with BSO or without BSO; Their last delivery was 24

months ago or before. Exclusion criteria: History of pelvic surgery; Severe heart or lung disease; Hematologic Disorders; Glaucoma; Asthma; liver disease; Endometriosis; Adnexal masses; history of myomectomy; Those who have taken GnRH agonist before surgery; allergy to misoprostol, Diastolic pressure above 100.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical sciences

Street address

Ghoreishi Department, Daneshgah street, Mashhad, Khorasan Razavi, Iran.

City

Mashhad

Postal code

9138813944

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MUMS.fm.REC.139

Health conditions studied**1****Description of health condition studied**

uterine myoma

ICD-10 code

N85-9

ICD-10 code description

Disorder of uterus NOS

Primary outcomes**1****Description**

changes of Hemoglobin

Timepoint

24 hours after interventional

Method of measurement

complete blood count

Secondary outcomes**1****Description**

bleeding during surgery

Timepoint

during surgery

Method of measurement

The amount of blood inside the suction device , The gravity of bloody sponges

Intervention groups**1****Description**

Intervention group: Fifty women who will Receive one pack of Misoprostol (400µg) before surgery.

Category

Treatment - Drugs

2**Description**

control group are 50 women who will receive one pack of Placebo before surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gynecology and Obstetrics, Imam Reza Hospital

Full name of responsible person

secretary

Street address

Gynecology and Obstetrics Department, Imam Reza Hospital, Taghi Abad Square, Mashhad, Khorasan Razavi, Iran.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

Street address

Ghoreishi Department, Daneshgah Street, Mashhad, khorasan razavi, Iran

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

dr. Salme Dadgar

Position

Faculty of University

Other areas of specialty/work**Street address**

Department of Gynecology and Obstetrics, Imam Reza Hospital , Mashhad, Iran.

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Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr Salme Dadgar

Position

Assistant professor of Obstetrics and Gynecology

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Full name of responsible person

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Position

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golhasanif1@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty