

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Intravaginal misoprostol reduces intraoperative blood loss in myomectomy .

Protocol summary

Summary

Objectives : Intravaginal misoprostol reduces intraoperative blood loss in myomectomy . Design : Interventional Setting & Conduct : Randomised-double blind . Use placebo . Single . Participants : Women with uterus myoma that sceduled for myamectomy . Inclusion criteria : Women with uterus myoma . Exclusion criteria : Virgin patient ; Sensitive to misoprostol ; Vaginal myomectomy ; Myomectomy assisted by hysteroscopy . Sample size : 64 Intervention : Insert vaginal misoprostol in cese group . Plasebo : Insert vaginal VIT B 6 in control group . Major outcome : Estimate blood loss with comparison of Hb befor & 6 & 12hour after operation . Secondary outcome : Reduction of operation time in case group .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100714927N1**
Registration date: **2013-11-27, 1392/09/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-27, 1392/09/06

Registrant information

Name

Shima Hajiha

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8831 3766

Email address

hajihashima@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-10-09, 1392/07/17

Expected recruitment end date

2014-01-10, 1392/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravaginal misoprostol reduces intraoperative blood loss in myomectomy .

Public title

Intravaginal misoprostol can reduces blood loss in myomectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Women with intramural or subsrosal uterus myoma that they are the case of laparatomy myomectomy . Exclusion criteria : Vaginal myomectomy ; Myomectomy assisted by hysteroscopy ; Virginity ; Misoprostol contraindications : liver diseas ; Epilepsy ; Sesnsitivity to misoprostol .

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 64

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

Ethics committee of Tehran university of medical sciences

Street address

Ghods avenue , Keshavarz blv , tehran .

City

Tehran

Postal code

Approval date

2013-09-28, 1392/07/06

Ethics committee reference number

1420-130-92-ص

Health conditions studied

1

Description of health condition studied

uterus myoma

ICD-10 code

D25.1 , D2

ICD-10 code description

D25.1 Intramural leiomyoma of uterus D25.2 Subserosal leiomyoma of uterus

Primary outcomes

1

Description

Hemoglobin count .

Timepoint

Hemoglobin before & 6 houre & 12 houerafter operation

Method of measurement

Blood examination

Secondary outcomes

1

Description

Operation time

Timepoint

Intraoperative

Method of measurement

Time

Intervention groups

1

Description

Intervention group : Intravaginal Misoprostol ; 200mig 3 hourse before operation .

Category

Treatment - Drugs

2

Description

Control group : Intravaginal Vit B6 (pelacebo) 3 hourse before operation .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Hospital

Full name of responsible person

Hajiha shima

Street address

Nejatollahi ave , Karimkhan ave , Tehran .

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Tehran University of Medical Sciences

Full name of responsible person

Hajiha shima

Street address

Nejatollahi ave , Karimkhan ave , Tehran .

City

Tehran

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 , Tehran 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**

Tehran university of medical sciences

Full name of responsible person

Hajihashima

Position

Resident of Obstetric & Gynecology

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

Women's Hospital , Nejatollahi ave , Karimkhan ave ,
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Fax**Email**

Hajihashima@yahoo.com

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

Tehran university of medical sciences

Full name of responsible person

Dr . Nasrin Niroomand

Position

Faculty member

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Tehran university of medical sciences

Full name of responsible person

Hajiha shima

Position

Resident of Obstetrics & Gynecology

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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