

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of vaginal misoprostol with oral misoprostol in cervical priming before hystroscopic surgery in postmenopausal women and perimenopausal women without history of Normal Vaginal Delivery.

Protocol summary

Summary

For comparison of vaginal misoprostol with sublingual misoprostol in cervical ripening before operative hysteroscopy in perimenopausal women without history of normal vaginal delivery and postmenopausal women : 120 patients with suspected intrauterine pathology who are candidate for operative hysteroscopy will be included in the study. They are randomly allocated in three groups: The first group receive 400 microgram misoprostol vaginally 10_12 hours before operation. The second group receive 400 microgram misoprostol sublingually 10_12 hours before operation and the third group receive no medication. Cervical width, number of patients needed cervical dilatation, duration of dilatation, operation time and complications are compared in the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204308588N6**
Registration date: **2012-06-14, 1391/03/25**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-06-14, 1391/03/25

Registrant information

Name

Mohadeseh Pishgahroudsari

Name of organization / entity

Mnimally Invasive Surgery Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 5447

Email address

research@lapsurg.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences.

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vaginal misoprostol with oral misoprostol in cervical priming before hystroscopic surgery in postmenopausal women and perimenopausal women without history of Normal Vaginal Delivery.

Public title

Effect of misoprostol in Cervical ripening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: menopausal women and perimenopausal women without history of normal vaginal delivery; who are not pregnant at the time of examination; do not have contraindications for prostaglandins (severe asthma, glaucoma, cardiac disease, hypertension or renal failure); do not have severe uterovaginal prolapse; do not have history of cervical surgery or cervical incompetency. Exclusion

criteria: history of normal vaginal delivery in perimenopausal women; pregnancy; have contraindications for prostaglandins (severe asthma, glaucoma, cardiac disease, hypertension or renal failure); have severe uterovaginal prolapse; have history of cervical surgery or cervical incompetency.

Age

From **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical science

Street address

Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

City

Tehran

Postal code**Approval date**

2012-04-14, 1391/01/26

Ethics committee reference number

14736

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

operative Hystroscopic Surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cervical Width

Timepoint

10-12 hours after intervention

Method of measurement

by surgeon during operation

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

Time of Dilatation

Timepoint

10-12 hours after Intervention

Method of measurement

By surgeon during operation

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

400 micro gram Vaginal misoprostol 10-12 hours before surgery

Category

Treatment - Drugs

2**Description**

400 Microgram sublingual 10-12 hours before surgery.

Category

Treatment - Drugs

3**Description**

No intervention

Category

Treatment - Drugs

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

Hazrat Rasool-e-Akram Hospital

Full name of responsible person**Street address**

Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences.

Full name of responsible person

Dr.Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Hazret Rasool-e- Akram Hospital

Full name of responsible person

Dr.Mahboobeh Saberi

Position

Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Minimally Invasive Surgery Research Center, Tehran University of Medical Sciences.

Full name of responsible person

Dr.Abolfazl Mehdizadeh Kashi

Position

Specialist of Gynecology

Other areas of specialty/work

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Person responsible for updating data

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Position

Expert Stats

Other areas of specialty/work

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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