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

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Name of organization / entity

Mnimally Invasive Surgery Research Center

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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences.
Full name of responsible person
Dr.Akbar Fotouhi
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Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.
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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

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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