

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of vaginal misoprostol with and without vaginal estrogen in cervical ripening before operative hysteroscopy in postmenopausal women

Protocol summary

Study aim

Comparison of vaginal misoprostol with and without vaginal estrogen in cervical ripening before operative hysteroscopy in postmenopausal women referring to Rasool-e Akram hospital

Design

Clinical trial with control group, with parallel groups, single blinded, randomized, phase 3 on 102 patients.

Settings and conduct

This study was performed on 102 postmenopausal women who were candidate for hysteroscopy in Rasool-e Akram hospital. Patients were randomly divided into two groups e.i. patients in the intervention group were treated with one third of 4 gr applicator of vaginal cream 0.625 mg estrogen conjugate + misoprostol and control group receive only misoprostol. Patients and statistical analysts were blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria were postmenopausal women (at least more than 1 year after the last menstrual cycle), candidates for hysteroscopy and patients must have a normal mammogram and Pap smear within the last 2 years. Exclusion criteria were recent or current pelvic infection, History of cervical conization, Previous surgery on the cervix, hypersensitivity to prostaglandins, History of venous thrombosis, Cardiovascular disease, Cervical or breast malignancies, Mullerian anomaly, Cervical anomalies

Intervention groups

Patients in the intervention group were treated with one third of 4 gr applicator of vaginal cream 0.625 mg estrogen conjugate + misoprostol. Control group receive only misoprostol.

Main outcome variables

Use of resectoscope, cervical softness, cervical stenosis, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211013052756N1**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **retrospective**

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

Registration date

2021-11-05, 1400/08/14

Registrant information

Name

Mahsa Kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 4111

Email address

dr.m.kiani87@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2021-01-19, 1399/10/30

Trial completion date

2021-04-21, 1400/02/01

Scientific title

Comparison of vaginal misoprostol with and without vaginal estrogen in cervical ripening before operative hysteroscopy in postmenopausal women

Public title

Comparison of vaginal estradiol in cervical ripening with misoprostol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal women (at least more than 1 year after the last menstrual cycle) Candidates for hysteroscopy Patients must have a normal mammogram and Pap smear within the last 2 years

Exclusion criteria:

Recent or current pelvic infection History of cervical conization Previous surgery on the cervix hypersensitivity to prostaglandins History of venous thrombosis Cardiovascular disease Cervical or breast malignancies Mullerian anomaly Cervical anomalies

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **102**

Actual sample size reached: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization with the permuted block method was used to create the random sequence and balance the number of allocated samples in intervention group (Vaginal misoprostol + estrogen, N=51) and control group (Vaginal misoprostol, N=51). The computer program was used for a random sequence using Excel, Rand function, in blocks of 2, 4, and 6. Each block has an equal number of control and HemoHIM groups. It is written on the cards and placed respectively for hiding in locked opaque packets. A packet was selected for each patient according to the study recruitment, which determines the related study group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient is unaware of the allocation of drugs because he/she will be anesthetized and the statistical analyzer will receive the groups in the form of codes A and B and is unaware of the type of intervention in the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No8,amani street, shariati street, tehran,iran.

City

Tehran

Province

Tehran

Postal code

۱۹۴۸۶۳۳۵۱

Approval date

2019-11-26, 1398/09/05

Ethics committee reference number

IR.IUMS.FMD.REC.1398.374

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Hegar cervical dilator during hysteroscopy

Timepoint

One during hysteroscopy

Method of measurement

Observation

Secondary outcomes

1

Description

Cervical softness and stenosis

Timepoint

One during hysteroscopy

Method of measurement

Observation

2

Description

Pain

Timepoint

One 6 hours after hysteroscopy

Method of measurement

Visual analogue scale

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

Intervention group: Patients in the intervention group were treated with one third of 4 gr applicator of vaginal cream 0.625mg estrogen conjugate (each 1gr contains 0.625 mg conjugated estrogen produced by Aburaihan pharmaceutical Co) for 5 days the week before surgery as daily consumption at home. Also, this group received 200 micrograms of vaginal misoprostol tablets (Sami Saz Pharmaceutical Co) 6 hours before surgery.

Category

Treatment - Drugs

2**Description**

Control group: This group received only 200 micrograms of vaginal misoprostol tablets (Sami Saz Pharmaceutical Co) 6 hours before surgery.

Category

Treatment - Drugs

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

Rasool-e-akram hospital

Full name of responsible person

Mahsa Kiani

Street address

No 8, Amani street , Shariati street. Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۹۴۸۶۴۳۴۵۱

Phone

+98 21 2286 4111

Email

dr.m.kiani87@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Vice- Chancellor in Research Affairs of Iran University of Medical Sciences, Next to Milad tower, Hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۴۸۶۴۳۴۵۱

Phone

+98 21 2286 4111

Email

keyvani.h@iums.ac.ir

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mahsa Kiani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No 8, Amani street, Shariati street , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1948643451

Phone

+98 21 2286 4111

Email

dr.m.kiani87@gmail.com

Person responsible for scientific inquiries**Contact**

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mahsa Kiani

Position
Resident
Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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No 8, Amani street, Shariati street, Tehran, Iran.

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dr.m.kiani87@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mahsa Kiani

Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available