Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
۱۹۴۸۶۴۳۴۵۱

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
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Email
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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