Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of evening primrose oil and misoprostol on cervical preparation before hysteroscopy and dilation and curettage

Protocol summary

Study aim

The aim of this study was to investigate the effect of evening primrose oil with misoprostol on cervical preparation before hysteroscopic and dilation and curettage surgeries.

Design

The clinical trial has a control group, with parallel groups, is double-blind, randomized, and is a phase 2 study that will be done on 100 patients.

Settings and conduct

Patients in the intervention group will be inserted vaginally in the back of the neck by the interventionist in sessions, 6 hours before the operation. In the control group, under the same conditions, 400 miligrams of misoprostol tablets will be inserted. For this clinical trial, the primary outcome is the dilatation rate and the secondary outcome is the average size of the first uterus. At the time of surgery, the size of the initial Hagar inserted into the internal os and the need to use mechanical dilatation to enter the hysteroscope into the internal os will be recorded by the surgeon.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18 to 75 years who were candidates for hysteroscopy and dilation and curettage. Exclusion criteria: Current pregnancy, cervical or vaginal infections, contraindications to misoprostol and EPO, cervical abnormalities and insufficiency, history of Müllerian type birth.

Intervention groups

Intervention group: In the group receiving evening primrose oil, 100mg-capsules are placed in the posterior fornix of the vagina, 6 hours before hysteroscopy. Control group: In the group receiving misoprostol, 400 micrograms suppository are placed in the posterior fornix of the vagina 6 hours before hysteroscopy.

Main outcome variables

Cervical opening preparation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240507061694N1**
Registration date: **2026-07-02, 1405/04/11**
Registration timing: **prospective**

Last update: **2026-07-02, 1405/04/11**
Update count: **0**

Registration date

2026-07-02, 1405/04/11

Registrant information

Name
Maede Hakimipour
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of evening primrose oil and misoprostol on cervical preparation before hysteroscopy and dilation and curettage

Public title

The effectiveness of evening primrose oil with misoprostol on cervical preparation before hysteroscopy and dilation and curettage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18-75 are candidates for hysteroscopy and dilation and curettage.

Exclusion criteria:

Current pregnancy Cervical or vaginal infections Contraindications for misoprostol and EPO Cervical abnormalities and insufficiency Previous Müllerian type birth

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to ease of use and saving time, the participants were divided into two groups using random sequence generation software. In this way, information such as the sample size and the number of groups is given to the software (Random allocation software) and the software provides a table of random numbers in which the letters A and B are randomly assigned to each number. In this study, numbers with letter A are in the intervention and numbers with letter B are in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial in which the participant, the outcome assessor and the data analyst will be unaware of the treatment process. After randomization, the patients of each treatment group are introduced by researcher 1 (orology resident) to researcher 2 to evaluate the outcome. Researcher 2 (the supervisor) is only an outcome assessor and records the results without knowing the type of treatment and its effects. A person who is an information analyst (statistician) also receives the recorded information at the end of the work and is not in the process of the intervention groups in any way. Drug injection will be done by an anesthesiologist. In each of the groups, the desired drugs is placed in the posterior fornix of the vagina by the resident 6 hours before hysteroscopy. The surgeon and the patients will not know the type of drug used, and before the surgeon enters, the removal of the probe and the drape will be done by another person, and if there is a vaginal pill, the pill will be removed so that the surgeon does not notice the presence of the vaginal pill and its type.Patients also do not know about the injectable substance.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Working Group/Research Ethics Committees, Faculty of Medicine and Faculty of Dentistry, Kashan Unive

Street address

Shahrdari Street, 15th Khordad Square, Kashan

City

Kashan

Province

Isfehan

Postal code

8713783976

Approval date

2024-04-07, 1403/01/19

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1403.001

Health conditions studied

1

Description of health condition studied

Hysteroscopy and dilation and curettage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The time to reach the required dilatation (4 to 8 mm)

Timepoint

From the start of the operation until reaching the required expansion

Method of measurement

Clinical

Secondary outcomes

1

Description
Cervical rupture
Timepoint
Immediately after the patient regains consciousness
Method of measurement
Clinical observations

2

Description
Perforation of the uterus
Timepoint
Immediately after the patient regains consciousness
Method of measurement
Clinical observations

3

Description
Side effects
Timepoint
Immediately after the patient regains consciousness
Method of measurement
Clinical observations

Intervention groups

1

Description
Intervention group: Intervention group: In patients of this group, 1capsules of 100 mg evening primrose oil (Abidi Pharmaceutical Company) are placed in the posterior fornix of the vagina by the resident, 6 hours before hysteroscopy
Category
Treatment - Drugs

2

Description
Control group: Control group: In patients of this group, Suppository of 400 micrograms of misoprostol (Samisaz Pharmaceutical Company) are placed in the posterior fornix of the vagina by the resident, 6 hours before hysteroscopy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital, Kashan
Full name of responsible person
Dr. Mansoureh Samimi
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2

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
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Vice chancellor for research, Kashan University of Medical Sciences, kilometr 5 balvar ghotab ravandi, Kashan
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Email
research@kaums.ac.ir
Web page address
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Grant name

Grant code / Reference number

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

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Maedeh Hakimipour

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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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
-

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