Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the effect of misoprostol and evening primrose oil on cervical dilatation before hysteroscopic surgery

Protocol summary

Study aim

The purpose of this study is to investigate the effect of misoprostol and evening primrose oil on cervical dilatation before hysteroscopic 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 120 patients.

Settings and conduct

In this clinical trial, 120 women referred to Kausar Medical Education Center located in Qazvin city are included in the study. The study population are women candidate for hysteroscopy who meet inclusion criteria. Using random allocation software, people are divided into two groups. In this study, both the surgeon and the patients do not know the type of drug used. For the purpose of blinding, 6 to 8 hours before hysteroscopy, the intended capsule is placed by the resident in the posterior fornix of the vagina. The removal of the prep and drape is done by another person, and if there is a vaginal pill, it will be removed so that the surgeon does not notice the presence of the vaginal pill and its type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Menopausal women or women of reproductive age with no history of normal vaginal delivery (NVD); Closure of the cervix. Non-inclusion criteria: Women with cervical structural abnormalities and a history of cervical insufficiency; women with Müllerian malformations

Intervention groups

Intervention group: In the group receiving evening primrose oil, 2 500mg-capsules are placed in the posterior fornix of the vagina, 6 to 8 hours before hysteroscopy. Control group: In the group receiving misoprostol, 2 mcg-capsules are placed in the posterior fornix of the vagina 6 to 8 hours before hysteroscopy.

Main outcome variables

Dilatation before hysteroscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230404057817N1**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **prospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

farkhondeh ghavampour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

kosarhospital284@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of misoprostol and evening primrose oil on cervical dilatation before hysteroscopic surgery

Public title
The effects of evening primrose oil in preparing the cervix before hysteroscopic surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Menopausal women or women of reproductive age with no history of normal vaginal delivery (NVD) Closure of the cervix
Exclusion criteria:
Women with cervical structural abnormalities and a history of cervical insufficiency Women with Müller malformations Women with a history of conization Women with any contraindications to EPO or misoprostol (EPO or misoprostol contraindications such as seizures, asthma, high blood pressure, glaucoma, etc.) Women who have a history of failed hysteroscopy or D&C due to severe cervical stenosis.
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
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
The study is double blind. In each of the groups, the desired capsule is placed in the posterior fornix of the vagina by the resident 6 to 8 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.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2023-03-06, 1401/12/15
Ethics committee reference number
IR.QUMS.REC.1401.341

Health conditions studied

1

Description of health condition studied
Hysteroscopy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The time to reach the required dilatation (3 to 7 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: In patients of this group, 2 capsules of 500 mg evening primrose oil (Abidi Pharmaceutical Company) are placed in the posterior fornix of the vagina by the resident, 6 to 8 hours before hysteroscopy.
Category
Treatment - Drugs

2

Description
Control group: In patients of this group, 2 capsules of 200 micrograms of misoprostol (Samisaz Pharmaceutical Company) are placed in the posterior fornix of the vagina by the resident, 6 to 8 hours before hysteroscopy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Farkhondeh Ghavampour
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Kosar Hospital, Taleghani St., Qazvin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Seyed Mehdi Mirhashmi
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Farkhondeh Ghavampour
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The collected information which is in the form of a questionnaire can be shared.
When the data will become available and for how long
The start of the access period is one year after the results are published.
To whom data/document is available
For obstetricians and researchers working in academic institutions
Under which criteria data/document could be used
Evaluate the path and process of study and analyze it
From where data/document is obtainable
For information, refer to Dr. Farkhondeh Ghavampour. The communication channels are as follows: By sending an email to the address: mahdieghavampoor@yahoo.com or referring and contacting Kosar Hospital at the address: Qazvin, Taleghani St. Phone: 028-33236374 Postal address: 34156-13176
What processes are involved for a request to access data/document
After sending the e-mail, the requested information will be reviewed by the facilitator and the person responsible for the scientific responsibility of the study. At your discretion, the requested information will be sent within 10 days of receiving the email
Comments