Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The evaluation of consuming evening primrose oil with misoprostol on cervical preparation before hysteroscopy

Protocol summary

Study aim
Comparison of evening primrose oil with misoprostol in cervical opening preparation in hysteroscopy candidate patients

Design
Clinical trial with control group with parallel groups, single blind, randomized phase 3 on 102 patients. The rand function of Excel software was used for randomization

Settings and conduct
Patients in the intervention group will be inserted vaginally in the back of the neck by the interventionist in two sessions, 6 and 2 hours before the operation. In the control group, under the same conditions, 200 micrograms 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
Women candidates for hysteroscopy Having informed consent to enter the study No need for laparoscopy - no pregnancy - - no cervical and vaginal infection - no bleeding disorders - no use of anticoagulants no epilepsy and blood pressure - no Anomalies and insufficiency of the cervix - absence of Müllerian anomalies - no ban on the use of prostaglandins Exclusion criteria: Lack of consent to continue studying

Intervention groups
In the intervention group, the effect of evening primrose capsules on cervical dilatation will be investigated. In the control group, misoprostol will be added to compare its effect with evening primrose capsules.

Main outcome variables
cervical opening preparation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240812062730N1**
Registration date: **2025-03-21, 1404/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-21, 1404/01/01**
Update count: **0**

Registration date
2025-03-21, 1404/01/01

Registrant information

Name
Nasrin hajiloo

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3346 3511

Email address
dr.n.hajiloo@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-26, 1403/07/05

Expected recruitment end date
2025-08-27, 1404/06/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The evaluation of consuming evening primrose oil with misoprostol on cervical preparation before hysteroscopy

Public title

The evaluation of consuming evening primrose oil with misoprostol on cervical preparation before hysteroscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for hystroscopy

Exclusion criteria:

Pregnancy Bleeding or trombofilic disease Inflammation in cervix or vagina Mulerian anomalies Hypertention or epilepsy Prohibition of using prostaglandins

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we make a column of random numbers, so the Rand() function is used in Excel. Then we will consider the random numbers below half as a block of 4 and the numbers above half as a block of 6. For this purpose, symbols A and B will be used for the intervention of evening primrose oil capsules and misoprostol tablets, respectively. The way of doing the work is that in a block of 4, two interventions A and two interventions B will be written in a column one after the other. Then, 4 random numbers will be assigned to this 4 column using the Rand() function. Then the order of assigned random numbers will be sorted from small to large so that the order of our intervention codes will also change. The same work will be repeated for the block of 6. This process continues until we reach an equal number of control and intervention groups. After generating random numbers without repetition, a number is assigned to each assigned sequence, which, along with the type of intervention received, is placed inside a sealed envelope, the contents of which are not known, so that the operating room nurse can qualify for each patient. He takes the condition of one of the 102 envelopes and after tearing the letter, informs the person in charge of prescribing the medicine of the intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidate patients are interviewed by the researcher when they visit. Patients are requested to participate in this study if they have consent. In case of patient's consent, first the goals and conditions of the study are explained to the patient and a written consent form is obtained from the patient. Then, using Excel software, the patients will be randomly assigned to two control (n=51) and intervention (n=51) groups. And the interventionist will insert the desired drugs, and as a result, only the participant from The type of intervention will be uninformed

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Hasani ave,urmia town

City

Urmia

Province

West Azarbaijan

Postal code

5715859497

Approval date

2024-08-06, 1403/05/16

Ethics committee reference number

IR.UMSU.REC.1403.138

Health conditions studied

1

Description of health condition studied

A study of cervical dilatation in hysteroscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of mechanical dilatation needed during hysteroscope entry

Timepoint

During hysteroscopy

Method of measurement

Using Hegar to enter internal OS and measure its size

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group will be inserted vaginally in the back of the neck by the interventionist in two sessions, 6 and 2 hours before the operation. In the control group, under the same conditions, 25 micrograms of misoprostol tablets will be inserted.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar hospital
Full name of responsible person
Kheyronnesa zibarzani
Street address
Hasani ave, Urmia town .kosar hospital
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Email
kosar.hospital@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber gholizade
Street address
Hasani ave urmia town kosar hospital
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Postal code
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Kosar.hospital@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Oroumia University of Medical Sciences
Full name of responsible person
Kheyronnesa zibarzani
Position
Assistant
Latest degree
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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data related to the main outcome will be shared
When the data will become available and for how long
From 2025
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
I do not have any special conditions in mind
From where data/document is obtainable
Refer to Dr. ZibArzani, personal information has already been registered
What processes are involved for a request to access data/document
After sending the email, the request will be answered
Comments