Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Evening primrose oil with Misoprostol on cervical ripening before hysteroscopy in women without a previous vaginal delivery. A double-blind clinical trial

Protocol summary

Study aim
Comparison of the effect of Evening primrose oil with Misoprostol on cervical ripening before hysteroscopy in women without a previous vaginal delivery

Design
A clinical trial with a control group; with parallel groups; double blind clinical trial; randomized; design of 100 patients; phase 3

Settings and conduct
For patients of both groups, the relevant questionnaires are completed before the start of the study. In the gynecology ward of Alzahra Hospital in Tabriz, medications are prescribed 4-6 hours before vaginal surgery (in the intervention group of evening primrose oil and in the control group of misoprostol). And the side effects of drugs are checked before, during and after the hysteroscopic operation and the general duration of cervical dilatation and the general duration of surgery and cervical dilatation and softness are checked .

Participants/Inclusion and exclusion criteria
Women candidates for hysteroscopy, 18-50 years old, non-pregnant, who have no history of natural childbirth or cervical manipulation, will be enter the study.Patients who have a history of history of molar cervical anomalies or history of a cervical biopsy will be prohibited from entering the study.

Intervention groups
Intervention group: 1 capsules of evening primrose 1000 mg (made by Dana Pharma company)The vagina is placed behind the fornix 4-6 hours before surgery. Control group:200 micrograms of misoprostol (Behestan Daru Company) 4-6 hours before surgery.

Main outcome variables
Complications of the drug before, during and after hysteroscopy; Cervical consistency; Cervical dilatation; Total duration of cervical dilatation; The total duration of surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220930056059N2**
Registration date: **2022-12-28, 1401/10/07**
Registration timing: **prospective**

Last update: **2022-12-28, 1401/10/07**
Update count: **0**

Registration date
2022-12-28, 1401/10/07

Registrant information
Name
Maryam Vaezi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-12-31, 1401/10/10
Expected recruitment end date
2023-12-31, 1402/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Evening primrose oil with Misoprostol on cervical ripening before hysteroscopy in women without a previous vaginal delivery. A double-blind clinical trial

Public title
Comparison of the effect of Evening primrose oil with Misoprostol on cervical ripening before hysteroscopy in women without a previous vaginal delivery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women candidates for hysteroscopy Candidate for hysteroscopy Aged 25-75 years non-pregnant The patient consent to participate in the study Who have no history of natural childbirth or cervical manipulation

Exclusion criteria:
Those who had a contraindication to PGs (history of severe asthma, glaucoma, preexisting cardiac disease, hypertension, or renal failure, bleeding disorders or consuming medications that inhibit blood clotting Patients with a history of schizophrenia who take phenothiazines patients with epilepsy and seizure Significant uterovaginal prolapse precluding the administration of vaginal tablets

Age
From **25 years** old to **75 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The treatment allocation list is already designed on Block Balanced Randomization Method by the computer software. 1 (A), 2 (B), 3 (B), 4 (B), 5 (A),..... Any eligible patient will be given a 1 to 100 code after obtaining informed consent in order to visit the clinic and based on the above block, they receive A or B drug. The drug distributor doesn’t have a role in the treatment plan and data analysis.Data analyzer are not aware of the type of treatment for each patient. Finally, the patients will be followed by their own codes

Blinding (investigator's opinion)
Double blinded

Blinding description
Outcome assessors and data analysts will not have information on how to assign groups to patients in groups A and B. We divide the outcome assessor and the patient data analyzer into A and B know and do not know the nature of groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Third Floor; Central Building of Number2; Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2022-11-14, 1401/08/23

Ethics committee reference number
IR.TBZMED.REC.1401.736

Health conditions studied

1

Description of health condition studied
Leiomyoma of uterus

ICD-10 code
D25

ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
Size of first input hegar dilator

Timepoint
At the beginning of the study and immediately after the hysteroscopy (4-6 hours after taking the drug)

Method of measurement
Measurement of cervical dilatation: Hegar dilator

Secondary outcomes

1

Description
Complications of the drug before, during and after hysteroscopy

Timepoint
After prescribing the drug (4-6 hours later) and immediately before the hysteroscopic surgery and during the operation
Method of measurement
Clinical observation

2

Description
Cervical consistency after drug administration
Timepoint
After prescribing the drug (4-6 hours later) and immediately before the hysteroscopic surgery and during the operation
Method of measurement
Check the consistency of the cervix with a finger examination, Hegar Dilator

3

Description
Duration of cervical dilatation
Timepoint
After prescribing the drug (4-6 hours later) and immediately before the hysteroscopic surgery and during the operation
Method of measurement
Timing

4

Description
The total duration of surgery
Timepoint
During the operation
Method of measurement
Timing

Intervention groups

1

Description
Intervention group: 1 capsules of evening primrose 1000 mg (made by Dana Pharma company)is inserted in the posterior fornix 4 to 6 hours before surgery.
Category
Treatment - Drugs

2

Description
Control group:200 micrograms of misoprostol (Behestan Daru Company) is inserted in the posterior fornix 4 to 6 hours before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr.Maryam Vaezi
Street address
Alzahra Hospital, South Artesh St.,Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Parviz Shahabi
Street address
No. 2 Central Building,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Maryam Vaezi

Position
Associate Professor of Obstetrics Gynecology

Latest degree
Subspecialist

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)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available