# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)

**Phone**
+98 41 3556 1831

**Email address**
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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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**Email**
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 scientific inquiries

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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