

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Assessing the Effect of evening primrose oil on the cervical ripening in patients without a history of vaginal delivery and who are candidate for hysteroscopy compared with the control group

#### Protocol summary

##### Summary

The goal of this study is to determine the effect of evening primrose oil (EPO) on the dilatation & ease of cervical ripening in patients who are candidates for hysteroscopy. The study population are 25-75 years old women who present to gynecology clinic of Hazrat Rasool hospital and are candidates for hysteroscopy. The patients are informed and assigned to 2 groups randomly. Inclusion criteria includes: post-menopausal women with closed cervix <3 mm dilatation), nulliparous and premenopausal women without history of normal vaginal delivery (NVD). Exclusion criteria includes: patients with history of NVD, contraindication for use of EPO (patient with bleeding disorder or medication that slows blood clotting, patient with schizophrenia, who receives phenothiazines/phenothiazine, epilepsy) and women with structural anomaly of the cervix. Calculated sample size has 42 patients (21 patients in each group). The study group receives two soft gels (500 mg each) of EPO vaginally in posterior fornix 6 hours before hysteroscopy and control group also receives placebo (placebo is EPO soft gels that evacuate and fill with distilled water). All patients will be going under general anesthesia. We will calculate the total time to achieve 10 mm dilatation of cervix with mechanical dilators and the size of first dilator that we have to insert more than medium force for each patient.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201308068588N16**  
Registration date: **2013-11-12, 1392/08/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-11-12, 1392/08/21

##### Registrant information

###### Name

Mohadeseh Pishgahroudsari

###### Name of organization / entity

Minimally Invasive Surgery Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6655 5447

###### Email address

research@lapsurg.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical sciences.

##### Expected recruitment start date

2013-08-06, 1392/05/15

##### Expected recruitment end date

2015-01-05, 1393/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the Effect of evening primrose oil on the cervical ripening in patients without a history of vaginal delivery and who are candidates for hysteroscopy compared with the control group

##### Public title

the effect of evening primrose oil on the ease of uterine

endoscopy

#### **Purpose**

Other

#### **Inclusion/Exclusion criteria**

Inclusion criteria: post-menopausal women with closed cervix, nulliparous and premenopausal women without history of NVD Exclusion criteria: patients with history of NVD, contraindication for use of EPO(bleeding disorder or medication that slow blood clotting, epilepsy ,patient with schizophrenia who receives phenothiazinsphenothiazine) and women with structural anomaly of the cervix :incompetent cervix , Mullerian anomaly of cervix and history of cervical conization.

#### **Age**

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

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **42**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of Medical sciences

##### **Street address**

Tehran University of Medical Sciences, corner of Ghods, Keshavarz Blvd., Tehran, Iran.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2013-10-21, 1392/07/29

#### **Ethics committee reference number**

94529

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

cervical ripening

#### **ICD-10 code**

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#### **ICD-10 code description**

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### **Primary outcomes**

#### **1**

#### **Description**

Total time to get 10 millimeters diameter dilatation of cervix

#### **Timepoint**

6 hours after intervention

#### **Method of measurement**

By Chronometer

#### **2**

#### **Description**

what size of dilators need to mid forced insertion

#### **Timepoint**

6 hours after intervention

#### **Method of measurement**

By dilator

### **Secondary outcomes**

#### **1**

#### **Description**

complication during insertion of dilators

#### **Timepoint**

after intervention

#### **Method of measurement**

observation

### **Intervention groups**

#### **1**

#### **Description**

In case group, 1000 mg Evening primrose oil (two soft gels) transvaginal, 6 hours before hystroscopy

#### **Category**

Treatment - Drugs

#### **2**

#### **Description**

In case group, two soft gels of plasebo transvaginal, 6 hours before hystroscopy

#### **Category**

Treatment - Drugs

### **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Rasool-e-Akram Hospital

**Full name of responsible person**

Dr.Kobra Tahermanesh

**Street address**

Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran university of Medical Sciences

**Full name of responsible person**

Dr.Motevalian

**Street address**

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran university of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Rasool-e-Akram Hospital

**Full name of responsible person**

Dr.Kobra Tahermanesh

**Position**

Fellowship of laparoscopy

**Other areas of specialty/work****Street address**

Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

Tehran

**Postal code****Phone**

+98 21 6435 2265

**Fax****Email**

floratary@yahoo.it

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Minimally Invasive Surgery Research Center

**Full name of responsible person**

Dr.Mansoureh Vahdat

**Position**

Obstetrics and Gynecologist

**Other areas of specialty/work****Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

Tehran

**Postal code****Phone**

+98 21 6435 2265

**Fax****Email**

mansoureh\_vahdat@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Minimally Invasive surgery research

**Full name of responsible person**

Dr.Kobra Tahermanesh

**Position**

Fellowship of laparoscopy

**Other areas of specialty/work****Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

Tehran

**Postal code****Phone**

+98 21 64351

**Fax****Email**

floratary@yahoo.it

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*