

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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Obstetrics and Gynecologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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Other areas of specialty/work

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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