Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Efficiency of Evening Primrose Oil on Cervical Ripening in Candidates for Operative Hysteroscopy: A Clinical Trial

Protocol summary

Study aim
Determining the efficiency of evening Primrose Oil on operative hysteroscopy

Design
Clinical trial with control group, with parallel groups, double blind, randomized

Settings and conduct
Location: Guilan university of medical sciences, Al-Zahra hospital, gynecology clinic. 160 eligible patients will be included in this study. participants were divided into two categories,Whether or not menopause and the randomization type is "Stratified Blocked Randomization ."In each category, eligible individuals during random allocation By blocked randomization will be allocated to the two groups receiving EPO and placebo. the study was double-blind so that patients and outcome evaluation specialist are unaware of the allocation status of the two groups to the study.

Participants/Inclusion and exclusion criteria
Inclusion criterias: women candidates for hysteroscopy
Exclusion criterias: people who need laparoscopy , no pregnancy, absence of systemic diseases, cervical and vaginal infection, patients with bleeding disorders, consumers of anticoagulants, schizophrenia who use phenothiazine , epilepsy, and blood pressure, anomalies and cervical insufficiency, Mullerian abnormalities and history of cervical biopsy, prohibition of prostaglandins and cesarean delivery.

Intervention groups
Intervention group: group A, 1000 mg EPO in soft gel capsule will receive posterior vaginal fornix 6 hours before hysteroscopy. Control group: group B will receive placebo in the same way as group A.

Main outcome variables
Factors examined include: interval of first resistance,duration of dilatation up to number10 hegar, duration of hysteroscopy, first hegar size ,ease of dilatation and need for mechanical dilatation as primary outcomes and cervical and uterine complications,side effects related to the drug used,pre-operative pain caused by drug use will be considered as secondary consequences.

General information

Reason for update
Enter a no entry criterion

Acronym

IRCT registration information
IRCT registration number: **IRCT20080910001233N5**
Registration date: **2019-08-29, 1398/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-07, 1400/05/16**
Update count: **1**

Registration date
2019-08-29, 1398/06/07

Registrant information

Name
Maryam Asgharnia

Name of organization / entity
Guilan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-06, 1398/05/15

Expected recruitment end date
2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficiency of Evening Primrose Oil on Cervical Ripening in Candidates for Operative Hysteroscopy: A Clinical Trial

Public title

Efficiency of Evening Primrose Oil on Operative Hysteroscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women candidates for hysteroscopy

Exclusion criteria:

People who need laparoscopy Pregnant women Existence of systemic diseases infection of cervix Existence of cervical anomalies Existence of Mullerian anomalies Contraindication prostaglandins. patients with bleeding disorders consumers of anticoagulants patients with schizophrenia who use phenothiazine patients With epilepsy patients With blood pressure People who need abdominal hysterectomy infection of vaginal Existence of cervical insufficiency Existence of history of cervical biopsy cesarean delivery History of allergies to evening primros

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

first, participants were divided into two categories,Whether or not menopause and the randomization type is "Stratified Blocked Randomization ". In each category, eligible individuals during random allocation By blocked randomization will be allocated to the two groups receiving EPO and placebo. The online site https://www.sealedenvelope.com will be used to generate a randomization list of study groups.Base on considering four blocks will be produced for 160 patients on site.

Blinding (investigator's opinion)

Double blinded

Blinding description

After generating the list, each person is assigned a unique code. None of the participants in the study will be aware of the randomization list , the groups are placed in closed envelopes in the admission section and eligible individuals who enter the study are included respectively.Therefore, the study was double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2019-07-17, 1398/04/26

Ethics committee reference number

IR.GUMS.REC.1398.193

Health conditions studied

1

Description of health condition studied

Hysteroscopy surgical facilitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

First resistance interval

Timepoint

Interval of first resistance based on duration to size of hegar dilator rejected without cervical resistance

Method of measurement

second

2

Description

Duration of dilatation to reach Hegar size 10

Timepoint

Interval from start of hysteroscopy hegar to create dilatation

Method of measurement

second

3

Description

Duration of hysteroscopy operation

Timepoint

Interval from the time of importing bogey to finishing importing bogey

Method of measurement

Minute

4

Description

First hegar size

Timepoint

During hysteroscopy

Method of measurement

Based on maximum dilator size (hegar),Which can be passed internal os without resistance.

5

Description

Ease of dilatation

Timepoint

During hysteroscopy

Method of measurement

Base on a 5-point Likert scale (excellent, good, average, poor, very poor)

6

Description

Requires mechanical dilatation

Timepoint

During hysteroscopy

Method of measurement

Based on clinical examination

Secondary outcomes

1

Description

Uterine and cervicovaginal complications (bleeding, uterine rupture, cervical rupture,false way) during surgery

Timepoint

during surgery

Method of measurement

See any of the unusual complications: bleeding , uterine rupture, cervical rupture,false way

2

Description

Side effects related to the drug used

Timepoint

During operation up to 24 hours after surgery

Method of measurement

Occurrence of any of the following undesirable effects: allergic reactions, abdominal pain, nausea, diarrhea, headache, increased bowel movements

3

Description

Preoperative pain from medication

Timepoint

Immediately before surgery

Method of measurement

Scoring for pain by the patient using VSA (Zero = no pain) and (ten = unbearable pain)

Intervention groups

1

Description

Intervention group: group A, 1000 mg EPO in soft gel capsule(two in each, 500 mg) will receive posterior vaginal fornix 6 hours before hysteroscopy.

Category

Treatment - Drugs

2

Description

Control group: group B will receive placebo (in the same size and shape) in the same way as group A.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Maryam Asgharnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Maryam Farrokhfar
Position
Resident of gynocologist Professor
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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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

There are no plans to share and publish it, yet

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the study results.

To whom data/document is available

All interested in study.

Under which criteria data/document could be used

No plans have been made for it yet.

From where data/document is obtainable

by Email

What processes are involved for a request to access data/document

Not yet planned for it.

Comments