Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Evening primrose oil with vaginal misoprostol in softening of the cervix in patients candidate for myomectomy hysteroscopy in Yas Hospital 2020-2022: a Randomized Clinical Trial

Protocol summary

Study aim

1. Comparison of Hegar dilator size used in Evening primrose oil group with misoprostol group 2. Determining the side effects caused by Evening primrose oil and misoprostol

Design

This phase 3 clinical trial with a control group, with parallel groups, double-blind, randomized using the Random allocation rule is performed on 118 patients.

Settings and conduct

In this randomized clinical trial study, which is performed on 118 patients who are candidates for myomectomy hysteroscopy in Yas Hospital from 2020 to 2022. The sampling method is a convenience method. This study is performed as a double-blind study, the surgeon (the person performing the hysteroscopy) and the patient do not know the type of treatment. The drug is used by the resident physician for the patient based on the patient group the night before the hysteroscopy.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all non-menopausal nulliparous women or gravid one women with a history of one cesarean section in the age group of 25 to 75 years. Criteria for not entering: Allergy or contraindication to Evening primrose oil or misoprostol

Intervention groups

In 59 patients 6 hours before hysteroscopy, for cervical ripening, two 500 mg Evening primrose oil capsules will be placed in the posterior part of the vagina, also, 200 micrograms of vaginal misoprostol will be used in the same way.

Main outcome variables

- Hegar dilator size used during hysteroscopy - Time to dilatation after taking the drug - Side effects following medication consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049169N1**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **prospective**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name
Elham Feizabad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8608 9092
Email address
elhamfeizabad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2022-11-21, 1401/08/30

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 vaginal misoprostol in softening of the cervix in patients candidate for myomectomy hysteroscopy in Yas Hospital 2020-2022: a Randomized Clinical Trial

Public title
Comparison of the effect of Evening primrose oil with vaginal misoprostol in softening of the cervix before myomectomy hysteroscopy in Yas Hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All non-menopausal nulliparous women or Gravid One women with a history of one cesarean section The age group of 25 to 75 years

Exclusion criteria:
people with a history of schizophrenia or epilepsy taking phenothiazines, structural cervical abnormalities such as a history of cervical insufficiency, Müllerian anomaly, and history of conization The unwillingness of people to participate in the study Allergy to Evening primrose oil or misoprostol contraindications for Evening primrose oil or misoprostol using such as coagulation disorders or concomitant consumption of anticoagulants drug

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

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **118**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation rule: First, 59 letters A and 59 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A or B are determined by a lot.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is performed as double-blind, the surgeon (the person performing the hysteroscopy), and the analyzer do not know the type of treatment. The drug is used by the resident physician for the patient based on the patient group the night before the hysteroscopy.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
ehran University of Medical Sciences,School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences,School of Medicine, Tehran Province, Tehran, Pour Sina St

City
Tehran

Province
Tehran

Postal code
1598718311

Approval date
2020-10-12, 1399/07/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.611

Health conditions studied

1

Description of health condition studied
Uterine Leiomyoma

ICD-10 code
D25

ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
The cervix dilatation measurement

Timepoint
Once, Before hysteroscopy

Method of measurement
The Hegar dilator size using for hysteroscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 6 hours before hysteroscopy for cervix ripening, 200 micrograms of vaginal misoprostol from Samisaz pharmaceutical company is placed in the

posterior part of the vagina.

Category

Treatment - Drugs

2

Description

Control group: 6 hours before hysteroscopy for cervix ripening two 500 mg capsules of Evening primrose oil from Daana pharmaceutical company is placed in the posterior part of the vagina.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Mehrnaz Valadan

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Fax

Email

mehrnaz_valadan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Valadan

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Email

mehrnaz_valadan@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sahar Garfami

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Email

sahar.garfami87@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Valadan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

City

Tehran
Province
Tehran
Postal code
1597856511
Phone
+98 21 8608 9089
Email
mehrnaz_valadan@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Feizabad
Position
Researcher
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave
City
Tehran
Province
Tehran
Postal code
1598718311
Phone
+98 21 8608 9089
Email
elhamfeizabad@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after unidentified participants
When the data will become available and for how long
After manuscript published
To whom data/document is available
No limitations
Under which criteria data/document could be used
The data is only available to the project manager, Dr. Valdan, and any analysis must be done with her opinion.
From where data/document is obtainable
Dr. Mehrnaz Valdan
What processes are involved for a request to access data/document
Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Valdan.
Comments