Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Primrose oil gel capsule on the Ease of Cervical Ripening Before Operative Hysteroscopy

Protocol summary

Study aim
The effectiveness of vaginal Evening primrose oil gel Capsule on the ease of Cervical Ripening

Design
A clinical trial with a control group; with parallel groups; double-blinded; 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 Hazrat Zeinab Hospital in Shiraz, 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
Inclusion criteria: Women candidates for hysteroscopy, 18-50 years old, non-pregnant, who have no history of natural childbirth or cervical manipulation, have spinal anesthesia and are satisfied with the participation. Exclusion criteria: contraindicated to use prostaglandins; history of molar cervical anomalies or history of a cervical biopsy; Patients receiving general anesthesia; BMI> 35

Intervention groups
In the gynecology ward of Hazrat Zeinab Hospital in Shiraz, 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.

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: **IRCT20140525017827N12**
Registration date: **2021-08-23, 1400/06/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-23, 1400/06/01**
Update count: **0**

Registration date
2021-08-23, 1400/06/01

Registrant information

Name
Nasrin Asadi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 1233 2365

Email address
asadin@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Primrose oil gel capsule on the Ease of Cervical Ripening Before Operative Hysteroscopy

Public title
Effect of eveing primrose oil in ripening of cervix before of gynecologic surgeries

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for hysteroscopy Aged 18-50 years No pregnancy Consent to participate in the study Women who do not have a history of normal delivery or cervical manipulation Spinal anesthesia nulliparity

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. History of cervical incompetence Mullerian anomaly or a history of a cervical cone biopsy, General anesthesia BMI>35

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Misoprostol and primrose oil gel capsules are the same appearance and characteristics and will be given to our colleague drug distributor in the form of A or B. 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. The patients, researcher, and 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
100 patients with incomplete abortion will be studied in two groups of 50. Patients will receive A or B medication based on randomized block in double blind method and a code will be allocated to each patient (1 to 100) that will be encoded at the end of the study. The patients and the designer and drug distributer are not aware of the drug pack. This study is the second phase of trial

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2020-07-14, 1399/04/24

Ethics committee reference number
IR.SUMS.REC.1399.685

Health conditions studied

1

Description of health condition studied
Cervical preparation before hysteroscopic surgery

ICD-10 code
N84.0

ICD-10 code description
Polyp of corpus uteri

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: 2 capsules of evening primrose 1000 mg (made by webber naturals Canada with confirmation code 1505809997164877771629, UID: 15210012004109455083 and GTN: 062600847248841 Food: LOT: 1 The vagina is placed behind the fornix 4-6 hours before surgery.
Category
Treatment - Drugs

2

Description
Intervention group: 400 micrograms of misoprostol (Pfizer company) 4-6 hours before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazat Zeinabeh Hospital of Shiraz University of Medical Science
Full name of responsible person
Omolbanin Hasani
Street address
Hazat Zeinabeh Hospital, Intersection defae moghadas, Shiraz
City
Shiraz
Province
Fars
Postal code
۷۱۵۳۸۱۳۳۱۱
Phone
+98 71 3726 5252
Email
banin.hassani5349@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbas Rezaeian Zade
Street address
Building of Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3235 7282
Email
rezaiana@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Omolbanin Hasani

Position
Shiraz

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3648 9830

Email
banin.hassani5349@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin Asadi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Email
nasadi2012@yahoo.ca

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin Asadi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8257

Email
nasadi2012@yahoo.ca

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Informed Consent Form
Yes - There is 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

Title and more details about the data/document
IPD: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long
IPD: 2021Ethic form: 2021

To whom data/document is available
IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used
IPD: Ethic form: Awareness of test results

From where data/document is obtainable

IPD: OB & Gyn ward Shiraz university of medical sciences Ethic form: OB & Gyn ward Shiraz university of medical sciences

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

IPD: Vice chancellery Ethic form: Vice chancellery

Comments