Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

A comparative study of misoprostol and evening primrose for cervical ripening before gynecologic procedures

Protocol summary

Study aim
A comparative study of misoprostol and evening primrose for cervical ripening before gynecologic procedures

Design
Clinical trial with parallel control group, double blind, randomized, Control with placebo, single center trial, Sample size 40 people.

Settings and conduct
Semnan Amiralmomenin Hospital. Two hours before the start of the procedure, one group is evening primrose (4 capsules) of mud and the other group is given misoprostol. Then patients will be expected to undergo gynecological surgery.

Participants/Inclusion and exclusion criteria
Pre-menopausal and post-menopausal women undergoing gynecologic surgery. Inclusion criteria: Women 25 to 75 years old; Candidate for gynecology surgery. Exclusion criteria: Heart disease, Liver, Asthma, Seizure; Infection; Bleeding Disorders; Taking anticoagulants.

Intervention groups
Intervention group: According to the protocol, they will receive evening primrose (4 capsules) vaginally 2 hours before surgery. Intervention group: According to the protocol, one tablet of misoprostol will be given intravenously 2 hours before surgery.

Main outcome variables
The rate of cervical opening.

General information

Reason for update
Hi The exact date was sampled corrected. Thanks

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N50**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **prospective**
Last update: **2022-05-24, 1401/03/03**
Update count: **1**

Registration date
2020-02-08, 1398/11/19

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

Phone
+98 23 3345 1336

Email address
are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-01, 1398/12/11

Expected recruitment end date
2021-01-23, 1399/11/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of misoprostol and evening primrose for cervical ripening before gynecologic procedures

Public title
A comparative study of misoprostol and evening primrose for cervical ripening before gynecologic procedures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women 25 to 75 years old Candidate for gynecology surgery

Exclusion criteria:

Heart disease, Liver, Asthma, Seizure Infection Bleeding Disorders Taking anticoagulants

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 4). Using Excel software to generate random number tables.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and clinical caregivers are unaware of the type of medication used in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.SEMUMS.REC.1398.156

Health conditions studied

1

Description of health condition studied

gynecologic

ICD-10 code

Z01.4

ICD-10 code description

Encounter for gynecological examination

Primary outcomes

1

Description

The rate of cervical opening

Timepoint

Before and after intervention

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: According to the protocol, they will receive evening primrose (4 capsules) vaginally 2 hours before surgery.

Category

Treatment - Drugs

2

Description

Intervention group: According to the protocol, one tablet of misoprostol will be given intravenously 2 hours before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan University of Medical Sciences

Full name of responsible person

Nahid Rahbar

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

Semnan

Province

Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Parviz Kokhaei
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
P_kokha@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Nahid Rahbar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Nahid Rahbar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Fatemeh Sharaf Shahi
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone

+98 23 3345 1336

Email

are20935@yahoo.com

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available