Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Evening Primrose Oil and Cervical Strip on Induction of Cervical Ripening and Birth Outcomes in Nulliparous Patients with Post-Term Pregnancies: A Clinical Trial Study

Protocol summary

Study aim

Determination of Bishop Score in Nulliparous Women Undergoing Evening Primrose Oil Intervention and Cervical Strip Before and After the Intervention

Design

A clinical trial with a control group, parallel groups, single-blind, randomized, was conducted on 46 patients. Block balanced randomization was used for patient randomization.

Settings and conduct

Women preparing for natural childbirth who attend the clinic at Imam Khomeini Hospital, Mazandaran University of Medical Sciences, Sari, Iran, will be randomly assigned to intervention and control groups. The intervention group will receive vaginal tablets inserted, while the control group will undergo a strip test. Patients are informed about the intervention and have given their consent, but the outcome assessor is unaware of the intervention, and blinding has been implemented.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Week 40 of pregnancy (from LMP or NT)،Women without contraindications for the use of evening primrose oil; Exclusion criteria: Rupture of fetal membranes during cervical preparation, Causing potential side effects from the medication, such as headaches

Intervention groups

Intervention group :Insertion of a 500 mg vaginal evening primrose oil capsule (Barij Essence Company, official packaging) into the cervix by the researcher control group:Cervical strip performed by a trained researcher every 48 hours

Main outcome variables

Bishop score average

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251218068375N1**
Registration date: **2026-02-17, 1404/11/28**
Registration timing: **prospective**

Last update: **2026-02-17, 1404/11/28**
Update count: **0**

Registration date

2026-02-17, 1404/11/28

Registrant information

Name

Zahra Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3337 0886

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z.rahmani1972@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effects of Evening Primrose Oil and Cervical Strip on Induction of Cervical Ripening and Birth Outcomes in Nulliparous Patients with Post-Term Pregnancies: A Clinical Trial Study

Public title
The Effect of Evening Primrose Oil on Cervical Ripening

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Week 40 of pregnancy (from LMP or NT) First pregnancy Willingness to participate in the study Age over 18 years A healthy pregnant woman without underlying conditions. Women without contraindications for the use of evening primrose oil There is no contraindication for natural childbirth. Singleton pregnancy Normal fetal heart rate pattern, absence of uterine contractions, healthy fetal membranes.

Exclusion criteria:
Rupture of fetal membranes during cervical preparation Causing potential side effects from the medication, such as headaches Individuals with a history of epilepsy

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
The patient randomization list will be generated using the block balanced randomization method with the help of the website Randomization.com, specifically from the original generator section, using blocks of four. The generated list will then be placed sequentially into sealed envelopes. After preparing the sealed envelopes, the list will be destroyed. The researcher who generates the randomization list will have no involvement in the intervention process. Patients will be enrolled in the study according to the order of the randomization list and the contents of the envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessor (second midwife or blinded gynecologist): examination and recording of Bishop score and other clinical outcomes

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences Ethics Committee

Street address
No. 245, Mazandaran University of medical Sciences, Joibar Bolvar, Sari

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Sari

Province
Mazandaran

Postal code
4817844718

Approval date
2025-11-26, 1404/09/05

Ethics committee reference number
IR.MAZUMS.REC.1404.436

Health conditions studied

1

Description of health condition studied
Childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Bishop score average

Timepoint
Once daily for a maximum of 5 consecutive days

Method of measurement
Vaginal examination and assessment of the Bishop score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Insertion of 500 mg vaginal capsules of evening primrose oil (Barij Essence Company, official packaging) by the researcher and evaluation for 5 days

Category
Treatment - Drugs

2

Description
Control group: Cervical strip performed by a trained researcher every 48 hours
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Zahra Rahmani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
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Web page address
https://jhc.mazums.ac.ir/person/28
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
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Associate professor
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no additional information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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