

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the Effect of Vaginal Capsule of Evening Primrose Oil and Misoprostol on Cervical Ripening of Nulliparous Women with Post-term Pregnancy

Protocol summary

Study aim

Comparison of the Effect of Vaginal Capsule of Evening Primrose Oil and Misoprostol on Cervical Ripening of Nulliparous Women with Post-term Pregnancy

Design

This study is a clinical trial with random allocation. Samples will be divided in two groups: Intervention, Control. Research community: Women with post term pregnancy admitting to maternity ward of Besat Hospital in Sanandaj in 2018. The sample size is 130 patients

Settings and conduct

Location: Sanandaj Besat Hospital. Single-blind clinical trial. Participation are unaware about intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy nulliparous women, Lack of contraindications for the use of evening primrose oil and misoprostol, Gestational age upper 40 weeks and 6 days, Single pregnancy and Live fetus, Cephalic presentation, Fetal heart rate pattern is normal, Absence of uterine contractions, Bishop Score lower than or equal to 4

Intervention groups

In the intervention group 500 mg capsule of evening primrose oil will implanted vaginally into posterior fornix and 25 micrograms of misoprostol to be given to the mother sublingually . In the control group 25 micrograms of misoprostol sublingually will be given and an empty capsule (placebo) will be placed vaginally in the posterior fornix. After 6 hours the Bishop scores will be evaluated and recorded. If there is necessary 2 doses will be repeated.

Main outcome variables

Effacement, Dillatation and Consistency of Cervix, Bishope score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180224038846N1**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **prospective**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Soma Bahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3377 3306

Email address

Bahmani.S@muk.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2639-06-22, 2018/04/01

Expected recruitment end date

2639-09-21, 2018/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Vaginal Capsule of Evening

Primrose Oil and Misoprostol on Cervical Ripening of Nulliparous Women with Post-term Pregnancy

Public title

Comparision of the Effect of Vaginal Capsule of Evening Primrose Oil and Misoprostol on Cervical Ripening of Nulliparous Women with Post-term Pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Healthy nulliparous women Lack of contraindications for the use of evening primrose oil Lack of contraindications for the use of misoprostol 40 weeks and 6 days of gestational age based on the date of the first day of the last menstruation or the first trimester ultrasonography Single pregnancy and live fetus Cephalic presentation Fetal heart rate pattern is normal Absence of uterine contractions Bishop score lower than or equal to 4 Intact membranes

Exclusion criteria:

Gestational age below 40 week and 6 days NST nonreactive

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to treatment with the toss of a coin

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be single blinded. The study consisted of two groups of intervention (Capsule of evening primrose oil and misoprostol) and The control group (Capsule of placebo and misoprostol) and Participants in this study will receive treatment that would be totally unaware.

Placebo

Used

Assignment

Parallel

Other design features

According to the searches made, No study has been conducted on the effect of evening primrose oil capsules on cervical ripening in post-term women in Sanandaj city and This research will be conducted for the first time in Sanandaj.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Kurdestan University of Medical Sciences- Pasdaran Street -Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

66166

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

ir.muk.rec.1396/367

Health conditions studied

1

Description of health condition studied

Post Term Pregnancy

ICD-10 code

O48.0

ICD-10 code description

Post-term pregnancy

Primary outcomes

1

Description

Cervical ripening rate

Timepoint

Every 6 hours as needed up to 3 doses

Method of measurement

In this study, cervical ripening was evaluated based on the evaluation of 5 components (dilatation, effacement, condition and strength and display station of the organ). Bishop score higher than 9 show the highest level of cervical preparation and lower than 4 suggest undesirable cervical status.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The nulliparous women with post-term pregnancy admitted to maternity ward of Besat hospital with less than 4 Bishop score will be the interventional group. For this group evening primrose oil

as a gelatin capsule (500 mg) vaginally will be inserted into posterior fornix and misoprostol 25 micrograms sublingually will be received.

Category

N/A

2

Description

Control group: The nulliparous women with post term pregnancy admitted to maternity ward of Besat hospital with less than 4 Bishop score will be control group. For this group placebo capsule vaginally will be inserted into posterior fornix and 25 micrograms misoprostol sublingually will be received.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital of Sanandaj-Kurdistan University of medical Sciences

Full name of responsible person

Soma Bahmani

Street address

Lale 1 Alley-26 Esfand Street-3/19-Baharan Town-Sanandaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Rezaei

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Soma Bahmani

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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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

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