Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparision 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
Comparision 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 Consistancy 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
Comparision 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

City

Sanandaj

Province

Kurdistan

Postal code

6617853471

Phone

+98 87 3377 3306

Email

Soma.bahmani25@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Rezaei

Street address

Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66166

Phone

+98 87 3377 3306

Email

Soma.bahmani25@gmail.com

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

Midwifery

Street address

Lale 1 Alley-29 Esfsnd Street-Baharan Town- Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

6617853471

Phone

+98 87 3377 3306

Email

Soma.bahmani25@gmail.com

Person responsible for scientific 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

Midwifery

Street address

Lale 1 Alley - 29 Esfand Street - 3/19 - Baharan Town -

Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code
6617853471
Phone
+98 87 3377 3306
Email
Soma.bahmani25@gmail.com

Person responsible for updating data

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
Midwifery
Street address
Lale 1 Alley-29 Esfand Street-3/19-Baharan Town-Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code
6617853471
Phone
+98 87 3377 3306
Email
Soma.bahmani25@gmail.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
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