Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Effect of vaginal evening primrose capsules on ripening of the cervix of nulliparous pregnant women

Protocol summary

Study aim
To determine the effectiveness of vaginal evening primrose capsules on ripening of the cervix of nulliparous pregnant women

Design
Clinical trials with drug and placebo control group, treatment-based, with parallel groups, blind, randomized by block method on 200 nuliparous pregnant women, enrolled between October 2018 and January 2020

Settings and conduct
This is a clinical trial study on nuliparous women attending to labor ward of Khaleej-e-fars hospital in Bandar Abbas. Participants will be randomly divided into two groups. One group will receive evening primrose oil vaginally and the other group will receive placebo. All participants will be blind to type of treatment. In order to blind the allocation, the pills will be divided into the opaque A and B packets and numbered. Participant, clinical caregiver, researcher, and outcome evaluator will be unaware of the type of intervention.The Bishop score of participants will be recorded before and 6 hours after the administration of drug and placebo.

Participants/Inclusion and exclusion criteria
Healthy low risk pregnant women with gestational age of 41 weeks attending to labor ward of Khaleej-e-fars hospital in Bandar Abbas

Intervention groups
Intervention group: Single dose of vaginal evening primrose oil capsule 1000 milligram Control group: Single dose of vaginal placebo

Main outcome variables
Bishop score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181107041585N3**
Registration date: **2020-04-07, 1399/01/19**
Registration timing: **retrospective**

Last update: **2020-04-07, 1399/01/19**
Update count: **0**

Registration date
2020-04-07, 1399/01/19

Registrant information

Name
Fatemeh Darsareh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3355 4515

Email address
famadarsareh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of vaginal evening primrose capsules on ripening of the cervix of nulliparous pregnant women

Public title
Effect of vaginal evening primrose capsules on ripening of the cervix

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Nuliparity 18-35 years old BMI 18.5-24.9 Kg/m2 Singleton pregnancy Gestational age of 41 weeks according to valid menstrual period or reliable first trimester pregnancy Alive fetus Cephalic presentation Intact amniotic fluid sac Reassure base non stress test Bishop score less than 4 No regular uterine contractions
Exclusion criteria:
Abnormal fetal heart changes in labor Abnormal maternal vital signs in labor Mecounial amniotic fluid Abnormal vaginal bleeding in labor
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple Random unit: Individual Randomization Tool: Sealed Envelope
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the allocation, the pills will be divided into the opaque A and B packets and numbered. Participant, clinical caregiver, researcher, and outcome evaluator will be unaware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Shafa Ave
City
Bandar abbas
Province
Hormozgan
Postal code
7918796758
Approval date
2020-03-19, 1398/12/29
Ethics committee reference number
IR.HUMS.REC.1398.487

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
Bishop score is the sum score of the place, dilation, effecment, position, and station of cervix to prognoses the ability of cervix for delivery
Timepoint
Before the administration of drugs and 6 hours after the administration of drug
Method of measurement
Bishop scoring scale

Secondary outcomes

1

Description
Method of delivery
Timepoint
After delivery
Method of measurement
Patients record

Intervention groups

1

Description
Intervention group: Administration of single dose of 1000 mg evening primrose oil capsule made by Natural-weber Canada company vaginally immediately after admission and after primery evaluation
Category
Treatment - Drugs

2

Description
Control group: Administration of single dose of placebo

vaginally immediately after admission and after primary evaluation

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Khaleeh fars hospital

Full name of responsible person
Fatemeh Darsareh

Street address
Pardis Blvd

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7919783141

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Email
famadarsareh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Teymoor Aghamolaeie

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Grant name
Technology and research vice-chancelory of Hormozgan University of Medical Sciences

Grant code / Reference number
970190

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Fatemeh Darsareh

Position
Midwife

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Position
Midwife

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Person responsible for updating data

Contact

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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
Confidentiality

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