

# 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 nulliparous pregnant women, enrolled between October 2018 and January 2020

##### Settings and conduct

This is a clinical trial study on nulliparous 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, effectment, 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

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7919783141

**Phone**

+98 76 3367 0285

**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

**Street address**

Shafa Blvd

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7919783141

**Phone**

+98 76 3367 0285

**Email**

taghamolaeie@yahoo.com

**Grant name**

Technology and research vice-chancellor 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 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