

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery in primiparous women

#### Protocol summary

Ripening of the cervix, duration of the first stage, second and third stages of the labor

#### Study aim

Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery in primiparous women referring to selected centers in sanandj, 2020

#### Design

This research will be conducted with the one-blind randomized trial method on 112 primiparous women referring to selected centers in sanandj. Samples will be divided into two equal groups of medicine and placebo with the randomized allocation method.

#### Settings and conduct

The study will be conducted in the office of two obstetricians and the Besat Hospital, and participants is not aware of the type of intervention.

#### Participants/Inclusion and exclusion criteria

Conditions for entering the study: - Willingness to participate in the study -Being primiparous -Literacy for reading and writing -Age 18 to 35 years old -Term pregnancy age based on first trimester ultrasound - Single pregnancy whit cephalic presentation -live fetus - Having a normal pelvis with a gynecologist's diagnosis - The estimated weight of the fetus is between 4000-2500 gr -Bishop score lower than or equal to 4 -Intact membranes -Healthy pregnant women -No ban on the use of evening primrose oil -No structural cervical anomalies -Height above 150 cm -Lack of alcohol and opioids -Avoid using laxatives and any herbal medication prior to study Conditions for not entering the study: - Mother's unwillingness to continue cooperation in the research -Consumption of less than two capsules per day -Use of epidural anesthesia -Cesarean delivery

#### Intervention groups

Intervention group: Each of the participants in the intervention group given to a bottle containing 14 1000mg oral evening primrose capsules. Control group: Each of the participants in the control group given to a bottle containing 14 placebo capsules containing canola oil.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200316046795N1**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **prospective**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

##### Registration date

2020-04-19, 1399/01/31

##### Registrant information

##### Name

Fatemeh Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 4233 4511

##### Email address

fateme.mohamadi@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-10-06, 1399/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery in primiparous women

**Public title**

Effect of oral evening primrose capsules on ripening of the cervix and progress of delivery

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate in the study Being primiparous  
Literacy for reading and writing Age 18 to 35 years old  
Term pregnancy age (gestational age 39 weeks to 39 weeks and 6 days) based on first trimester ultrasound  
Single-pregnancy whit cephalic presentation live fetus  
Having a normal pelvis with a gynecologist's diagnosis  
The estimated weight of the fetus is between 4000-2500 grams  
Bishop score lower than or equal to 4 Intact membranes  
Healthy pregnant women (without known disease, surgery or pregnancy complications such as placental abruption, placenta previa or vasoprevia , preeclampsia or no fetal anomaly)  
No ban on the use of evening primrose oil (hemorrhagic disorders, consuming anticoagulants, individuals with a history of schizophrenia, epilepsy and consumer phenothiazine)  
No structural cervical anomalies  
Height above 150 cm  
Lack of alcohol and opioids  
Avoid using laxatives and any herbal medication prior to study

**Exclusion criteria:**

Mother's unwillingness to continue cooperation in the research  
Consumption of less than two capsules per day (problems with checklist of oral capsules)  
Use of epidural anesthesia  
Cesarean delivery

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **112**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals will be divided into intervention and control groups using the quadratic block formation method. A code to intervention (using capsules of evening primrose) and Code B to the control group (using placebo) will be allocated. The four blocks will then be sampled in six different modes (AABB, ABAB, ABBA, BBAA, BABA and BAAB).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This research is a with the one-blind randomized trial method (participants will be unaware of the contents of the capsules). For this purpose to observe the ethical issues of the research, after the necessary explanations about the purpose and how to conduct the study to pregnant mothers, informed consent is obtained from them. Samples are divided into two equal groups of medicine and placebo with the randomized allocation method. Each of the participants will be given a bottle containing 14 1000mg oral evening primrose capsules (2 capsules per day, each 12 twelve hours for a week) or the placebo containing 14 placebo capsules containing canola oil. The color and shape of these capsules are similar to the intervention group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kurdistan University of Medical Sciences

**Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences, School of Nursing and Midwifery

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617913446

**Approval date**

2020-03-15, 1398/12/25

**Ethics committee reference number**

IR.MUK.REC.1398.309

**Health conditions studied****1****Description of health condition studied**

Ripening of the cervix and progress of labor

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Ripening of the cervix

**Timepoint**

Bishop score is recorded at the beginning of the study and then, if there are no labor symptoms, the Bishop score is measured again after one week.

#### **Method of measurement**

The second part of the questionnaire: Midwifery Specifications (Bishop Score)

## **2**

#### **Description**

Labor progress

#### **Timepoint**

Registration of vaginal examinations at the beginning of the study and then in the active phase of the first stage of labor will be done every 2 hours and in the second stage of labor every 30 minutes. The registration of uterine contractions and fetal heart rate at the beginning of the study will be once every 30 minutes in the active phase of the first stage of labor and once every 15 minutes in the second stage of labor.

#### **Method of measurement**

The third part of the questionnaire (delivery details)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Capsule of evening primrose oil group: Evening primrose oil capsules are produced by pharmaceutical companies Barij. Providing a capsule in the beginning of the study, if the criteria for entry into the study. Each of the participants in the intervention group given to a bottle containing 14 1000mg oral evening primrose capsules (2 capsules per day, each 12 twelve hours for a week).

#### **Category**

Prevention

### **2**

#### **Description**

Control group: Placebo group: The capsules used for the control group are prepared by the researcher that the color and shape of these capsules are similar to the intervention group. Providing a capsule in the beginning of the study, if the criteria for entry into the study. Each of the participants in the control group given to a bottle containing 14 placebo capsules containing canola oil (2 capsules per day, each 12 twelve hours for a week).

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

#### **Name of recruitment center**

Dr. Sholeh Shah Ghaibi's office

#### **Full name of responsible person**

Roonak Shahoei

#### **Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

#### **City**

Sanandaj

#### **Province**

Kurdistan

#### **Postal code**

6617913448

#### **Phone**

+98 87 3362 7636

#### **Fax**

+98 87 3366 0092

#### **Email**

Rshaho@yahoo.com

### **2**

#### **Recruitment center**

#### **Name of recruitment center**

Dr. Fariba Farhadifar's office

#### **Full name of responsible person**

Roonak Shahoei

#### **Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

#### **City**

Sanandaj

#### **Province**

Kurdistan

#### **Postal code**

6617913448

#### **Phone**

+98 87 3362 7636

#### **Fax**

+98 87 3366 0092

#### **Email**

Rshaho@yahoo.com

### **3**

#### **Recruitment center**

#### **Name of recruitment center**

Besat Hospital

#### **Full name of responsible person**

Roonak Shahoei

#### **Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

#### **City**

Sanandaj

#### **Province**

Kurdistan

#### **Postal code**

6617913448

#### **Phone**

+98 87 3362 7636

#### **Fax**

+98 87 3366 0092

**Email**  
Rshaho@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Ebrahim Ghaderi

**Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617913448

**Phone**

+98 87 3362 7636

**Fax**

+98 87 3366 0092

**Email**

Rshaho@yahoo.com

**Web page address**

<http://www.muk.ac.ir/Page?pagelid=33>

**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**

Roonak Shahoei

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Sanandaj, Pasdaran Street, Kurdistan University of Medical Sciences, School of Nursing and Midwifery

**City**

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Kurdistan

**Postal code**

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**Fax**

+98 87 3366 0092

**Email**

Rshaho@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Roonak Shahoei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

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**Position**

Associate professor

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Ph.D.

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All data can be shared after persons have not been recognized.

**When the data will become available and for how long**

Data access is 6 months after publish the results.

**To whom data/document is available**

Data will only be available to researchers working at academic and scientific institutions.

**Under which criteria data/document could be used**

Access to data requires observe of professional ethics fundamental.

**From where data/document is obtainable**

Applicants can refer to the library of the Faculty of Nursing and Midwifery of Kurdistan University of Medical Sciences or Dr. Roonak Shahoei to receive the data.

Address: Kurdistan University of Medical Sciences Email: Rshao@yahoo.com Phone:087- 33627636

**What processes are involved for a request to access data/document**

The documents applicant can access that after the article is published.

**Comments**