

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Investigation the Effect of vaginal Evening Primrose capsule on cervix preparation in nulliparous Women

#### Protocol summary

##### Study aim

Determining the effect of vaginal Evening Primrose capsule on Bishop score in nulliparous women.

##### Design

Clinical trial with a control group, community-based and pragmatic, with parallel groups, double-blind, randomized

##### Settings and conduct

Study population contains all the pregnant women who would refer to the health centers of Rafsanjan. So 86 women, with regard to the inclusion and exclusion criteria, would be enrolled in the study using convenient method and then would be allocated into two groups of control and intervention using simple randomization. Training about the method of placing the Primrose capsule and placebo in the posterior fornix would be conducted using a replica in the intervention and control groups, and they would be advised to use one Primrose capsule or placebo every night before sleeping from the 38th week of pregnancy until the birth symptoms occur. The participants and the individuals in charge of distributing the capsules would not be aware of the control and intervention groups' allocation. Information about the Bishop score would be extracted from the delivery file of women and related forms would be completed.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: willingness to participate in the study, willingness to have vaginal delivery and being 18-35 years old The exclusion criteria: not taking two consecutive capsules of Evening Primrose.

##### Intervention groups

Intervention group: Daily vaginal use of 1 capsule of prime Rose every night before bedtime from the 38th week of pregnancy until the time of delivery Control group: Using placebo in the same manner as the intervention group

##### Main outcome variables

Bishop score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160308026971N4**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

##### Registration date

2018-06-10, 1397/03/20

##### Registrant information

##### Name

Marzeyeh Loripoor

##### Name of organization / entity

Rafsanjan University Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3428 4950

##### Email address

m.loripoor@rums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Research Deputy of Rafsanjan University of Medical Sciences

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-06-22, 1397/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigation the Effect of vaginal Evening Primrose capsule on cervix preparation in nulliparous Women

### Public title

Investigation the Effect of vaginal Evening Primrose capsule on cervical preparation for childbirth

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Inclination to participate in the study  
Tendency to normal delivery  
Selection of Niknafs hospital for delivery  
Mother's age is 18-35 years  
Gestational age 38 weeks based on first trimester Ultrasonography or reliable IMP  
Single fetus with cephalic presentation  
The basis of the results of the last ultrasound  
Nulliparity the integrity of the embryonic membranes

#### Exclusion criteria:

Non-use of two successive capsules of Primrose  
Primrose capsule susceptibility  
Emergency intervention for maternal or embryonic reasons  
Unwillingness of the research unit to continue cooperation  
Vaginal bleeding  
Presence of contraindications for use of Evening Primrose capsule (diseases associated with disorders Hemorrhagic agents, anticoagulant drugs, Patients with history of psychiatric disorders in the phenothiazine category, and epilepsy patients)  
History of known chronic disease  
Pregnancy complications such as Hydromenosis, Oligohydroamenia, Pre-eclampsia, Eclampsia

### Age

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

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: **86**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The method of random allocation in this study is simple randomization and its tool is a random number table. At first, the researcher referred to the public health centers of Rafsanjan (Nos. 1, 4, and 5). She chose all the eligible pregnant women in the apple system and, after telephone conversation with each of the women, explained the research, if Their willingness to participate in the study, each of them assigned a number, and then the random numbers table is used to select the members of the intervention and control group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, the research units and the clinical caregiver are unaware of any sample in which of the control and

intervention groups.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Rafsanjan University Medical Science

##### Street address

Imam Ali street, cenral department of Rafsanjan University Medical Science

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717932777

#### Approval date

2017-08-05, 1396/05/14

#### Ethics committee reference number

IR.RUMS.REC.1396.89

## Health conditions studied

### 1

#### Description of health condition studied

Bishop Score

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Bishop score

#### Timepoint

After intervention

#### Method of measurement

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The drug used in this study is soft Barich EPO capsule or Evening Primrose Oil capsule produced by Barich Essence Company. Each soft capsule contains 1000 mg of Evening Primrose Oil and 140-70 mg gamma linolenic acid (GLA). Each study unit in the intervention group is given 21 units. From the beginning of the 38th week of gestation until the day of delivery, one capsule of Evening Primrose Oil embeds in the posterior fornix.

#### Category

Treatment - Drugs

### 2

#### Description

Twenty-one placebos are presented to the control group in the same way as Evening Primrose Oil capsule, manufactured by the Barich Essence pharmaceutical company, From the beginning of the 38th week of gestation until the day of delivery, one placebo of Evening Primrose capsule embeds in the posterior fornix.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health center No.1

##### Full name of responsible person

Motahare Najafi

##### Street address

Health Center No. 1, Imam Khomeini Street, Ghods Square

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717653548

##### Phone

+98 34 3429 4081

##### Email

ava.man623@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Health center No.4

##### Full name of responsible person

Motahare Najafi

##### Street address

Health Center No. 4, West Amir Kabir Street, facing the children's park

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718663316

#### Phone

+98 34 3432 5911

#### Email

marzeyehloripoor@yahoo.com

### 3

#### Recruitment center

##### Name of recruitment center

Health center No.5

##### Full name of responsible person

Motahare Najafi

##### Street address

Health Center No. 5, Kargar Street

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7716676788

##### Phone

+98 34 3425 3035

##### Email

1372najafi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Dr. Ali Shamsizadeh

##### Street address

Imam Ali Blvd., Dept. of Research & Technology, Central Office of Rafsanjan University of Medical Sciences,

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717933777

##### Phone

+98 34 3428 0097

##### Fax

+98 34 3428 0097

##### Email

alishamsy@gmail.com

##### Web page address

<http://vcrt.rums.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rafsanjan 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**  
Faculty of Nursing and Midwifery  
**Full name of responsible person**  
Marzeyeh Loripoor  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Nursing and Midwifery University, Nursing Street  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7718796755  
**Phone**  
+98 34 3428 5900  
**Fax**  
+98 34 3425 8497  
**Email**  
marzeyehloripoor@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Faculty of Nursing and Midwifery  
**Full name of responsible person**  
Marzeyeh Loripoor  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Faculty of Nursing and Midwifery, Nursing street  
**City**  
Rafsanjan  
**Province**

Kerman  
**Postal code**  
7718796755  
**Phone**  
+98 34 3428 5900  
**Fax**  
+98 34 3425 8497  
**Email**  
marzeyehloripoor@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Faculty of Nursing and Midwifery  
**Full name of responsible person**  
Marzeyeh Loripoor  
**Position**  
PHD Reproductive Health  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Faculty of Nursing and Midwifery, Nursing street  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7718796755  
**Phone**  
+98 34 3428 0035  
**Fax**  
+98 34 3425 8497  
**Email**  
marzeyehloripoor@yahoo.com  
**Web page address**

## 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**  
There is not more information  
**Study Protocol**  
No - There is not a plan to make this available  
**Statistical Analysis Plan**  
No - There is not a plan to make this available  
**Informed Consent Form**  
No - There is not a plan to make this available  
**Clinical Study Report**  
No - There is not a plan to make this available  
**Analytic Code**  
No - There is not a plan to make this available  
**Data Dictionary**  
No - There is not a plan to make this available