

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### A comparative study on the effect of oral and vaginal of primrose oil capsule on bishap score and some prenatal outcomes in nulliparous women

#### Protocol summary

##### Study aim

A comparative the effect of primrose oral and vaginal capsule on Bishop score and some delivery outcomes in primiparous women referring to the NiknafsRafsanjan maternity hospital

##### Design

Randomized Clinical Trial with two intervention groups and one control group; Three blindsides; Parallel groups; Permuted block randomization

##### Settings and conduct

The statistical population of the research; Includes all nulliparous pregnant women referring to Comprehensive health service centers in Rafsanjan. The sample size will be estimated based on the statistical formula (35 people in each group). This research will be a triple-blind study. In order to blinding, the pharmacist will be asked to define the medicines and placebo with group A\_B\_C and will put the prescription of them inside each package. Blinding will be done for the researcher, samples, clinical caregiver, and analyzer.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to normal vaginal delivery; Mother age:18-35 years; Pregnancy age: 38 weeks based on reliable first-trimester ultrasound; Single-fetal with a cephalic presentation based on the latest ultrasound results. Exclusion criteria: oligohydramnios; preeclampsia; eclampsia; vaginal bleeding.

##### Intervention groups

The first intervention group consumes two oral capsules contains one gram of Primrose oil daily. The second intervention group consumes two vaginal capsules contains one gram of Primrose oil daily. The control group consumes two Placebo capsules "similar" and containing one gram of sunflower oil

##### Main outcome variables

Bishop's score; The length of the first stage of delivery; The length of the second stage of childbirth; Frequency

of normal vaginal delivery; Instrumental delivery; Meconium aspiration; Need to induction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190717044248N5**

Registration date: **2021-04-18, 1400/01/29**

Registration timing: **retrospective**

Last update: **2021-04-18, 1400/01/29**

Update count: **0**

##### Registration date

2021-04-18, 1400/01/29

##### Registrant information

##### Name

Zahra Saghafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

z.saghafi@rums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-05, 1399/05/15

##### Expected recruitment end date

2021-03-05, 1399/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
A comparative study on the effect of oral and vaginal of primrose oil capsule on bishap score and some prenatal outcomes in nulliparous women

**Public title**  
A comparative study on the effect of oral with vaginal of primrose oil capsule on bishap score and some prenatal outcomes

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Willingness for participant in the study Willingness to normal vaginal delivery Mother age between 18-35 years Pregnancy age: 38 weeks based on reliable first-trimester ultrasound or last menstrual period Single-fetal with a cephalic presentation based on the latest ultrasound results  
**Exclusion criteria:**  
Contraindications of primrose oil capsule Sensitivity to primrose oil capsule known history of psychological illness Delivery complications such as polyhydramnios, oligohydramnios, preeclampsia, eclampsia, vaginal bleeding History of having confirmed phsycological disorders Having any psychological disorders in the time of participation Having epilepsy

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

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **105**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Individuals who will have the inclusion criteria will be selected with the Convenience Sampling method. The Permuted block randomization will be used to allocate people to three groups. In this study, seven blocks (every block has 15 paces) will be created, so that after determining Individuals who will have the inclusion criteria, the first 15 people who enter the study will be divided into three groups randomly (assigning 5 people to each group), then the next 15 people will be divided into three groups randomly in the same way, and this method will be continued until the last block. The output of the software will be English letters (A, B & C) and each

letter will be the representative of one of the intervention or control groups.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
At first, participants will be justified about the study, and will be informed consent will be taken. For blinding, the pharmacist will be asked to identify the medicine and placebo with the A\_B\_C group and the prescription in each package will be placed. So that the researcher would not know about the content of packages (medicine or placebo). The medicine is also will be given to participants as A or B or C, and participants will not be informed of the content of packages (medicine or placebo). This blinding will also be available for the analyzer, and after finishing the statistical analysis the content of packages (medicine or placebo) will be asked from pharmacists.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Rafsanjan University of Medical Sciences

**Street address**  
Emam Ali Blvd, Rafsanjan

**City**  
Rafsanjan

**Province**  
Kerman

**Postal code**  
77179335777

**Approval date**  
2019-06-17, 1398/03/27

**Ethics committee reference number**  
IR.RUMS.REC.1398.052

**Health conditions studied**

**1**

**Description of health condition studied**  
Normal Vaginal Delivery

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

## 1

### Description

Mean Bishop score

### Timepoint

It will be measured in active phase of delivery time.

### Method of measurement

Bishop score is obtained by scoring the five criteria of dilatation, effacement, fetal head station, softness, and cervical position during vaginal examination.

Accordingly, each of the first three criteria is given a score of 0-3 and each of the following two criteria is given a score of 0-2.

## 2

### Description

The frequency of spontaneous onset of labor

### Timepoint

Time of delivery

### Method of measurement

Check list

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group: Two capsules contains one gram of oral Primrose oil, made by Barich Essence Company, which patients consume from night to night starts from 38 weeks to delivery time. If a person forgets to consume for two days, it will be removed from the study.

#### Category

Treatment - Drugs

### 2

#### Description

The second intervention group will receive two Prime rose capsules (vaginal ,1000 mg, daily) made by Barich Essence Company. Participants will consume from night to night starts from 38 weeks to delivery time. If a person forgets to consume for two days, it will be removed from the study.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Niknafs maternity center of Rafsanjan

##### Full name of responsible person

Zahra Hajbagheri

##### Street address

No. 54, 16th Alley, South Meraj Ave.

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7719655585

##### Phone

+98 34 3422 2321

##### Email

azamsharifi.967@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Shamsizadeh

##### Street address

Deputy of research and technology, Building Num 3, Central Organization of University of Medical Sciences, Imam Ali Blvd

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718146890

##### Phone

+98 34 2834 7200

##### Email

vcrt@rums.ac.ir

#### Grant name

Rafsanjan University of Medical Sciences

#### 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

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Fareeba Payhdar

**Position**

Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Nursing and midwifery school, Sahely Blvd, Motahari Street

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Email**

f.payedar73@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Zahra Saghafi

**Position**

Totur

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Nursing and midwifery school, Sahely Blvd, Motahari Street

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Email**

saghafiz@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Hossein Ghaedamini

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No. 30, 15th Yadeghar Alley, Yadegar Emam Ave, Yadegar Emam Town

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7714186759

**Phone**

+98 34 3434 0454

**Email**

ghaedaminih@gmail.com

**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 of information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable