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 NiknafsRafsajan 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
Street address
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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
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Position
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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 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