

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A Comparative investigation of the effect of oral vening primrose oil capsules with vaginal form before induction on Bishop's score, the success of induction, and some outcomes of labor in women.

Protocol summary

Study aim

Determination and Comparative investigation of the effect of oral with vaginal form evening primrose oil capsules before induction on Bishop's score, the success of induction and some outcomes of labor in women referred to the Niknafs Maternity hospital of Rafsanjan city in 2019

Design

Randomized clinical trial, phase 3, 100 samples with two intervention groups, without control group, double blind

Settings and conduct

This study is a double blind randomized clinical trial based on Bishop's score and number of normal vaginal delivery. The first intervention group will receive two Prime rose capsules (oral, 1000 mg, daily) and the second intervention group will receive two capsules (vaginal, 1000 mg) at the time of induction. The location of this study is NickNafs Rafsanjan maternity hospital

Participants/Inclusion and exclusion criteria

1. Willingness to participate in the study 2. Compete Inform consent 3. Mother age of 18-35 years 4. Normal amniotic cyst 5. Normal ECG in the fetus 6. Lack of labor contraction 7. Low-risk pregnancies such as lack of a (placenta previa, diabetes, preeclampsia, decreased fetal movement, reduced amniotic fluid ...) 8. Single-fetus with a cephalic presentation based on the latest ultrasound results 9. Bishop score less than 6 10. Negative past medical history of known chronic diseases 11. Persian Race Exclusion criteria: 1. The need for emergency intervention for maternal or fetal reasons before induction 2. Birth weight less than 2500 and above 4000 grams

Intervention groups

The first intervention group will receive two 1000 mg oral rose capsules and the second intervention group will receive two 1000mg vaginal prime rose capsules at the same time with induction

Main outcome variables

The mean Bishop score, Success of labor induction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044248N4**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Zahra Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3425 5900

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-04, 1399/05/14

Expected recruitment end date

2021-03-04, 1399/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A Comparative investigation of the effect of oral vening primrose oil capsules with vaginal form before induction on Bishop's score, the success of induction, and some outcomes of labor in women.

Public title
A Comparative investigation of the effect of oral vening primrose oil capsules with vaginal form before induction on Bishop's score, the success of induction, and some outcomes of labor.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness for participant in the study
Willingness to normal vaginal delive
Mother age between 18-35 years
Normal amniotic cyst
Normal ECG of fetus
No labor contraction
Low risk pregnancy
Single-fetus
Cephalic presentation based on the latest ultrasound results
Bishop score less than 6
Iranian race
Selection of Niknafs Maternity Center of Rafsanjan as the place of delivery
Exclusion criteria:
Contraindications of Gelax consumption
Sensitivity to Gelax capsules
known history of psychological illness
Delivery complications such as polyhydramnios, oligohydramnios, preeclampsia, eclampsia, vaginal bleeding
History of having confirmed psychological disorders
The need for emergency intervention for maternal or fetal reasons before induction
Birth weight less than 2500 and above 4000 grams
Having labor contractions

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

Gender
Female

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random classification by minimization method: Among those who refer to the maternity hospital to induce labor, people who have the inclusion criteria, Will be selected as a research sample. In order to allocate individuals to groups A or B, the first person in each of the quadrupled stratum will be randomly entered into the study by flip a coin. To allocate the next samples to groups A or B, the sum of the number of samples, ie the number of

pregnancies and the bishop score, is considered in the quadrupled stratum, and the next sample will belong to the class that has the least sum. If the samples are equal in stratum, the same routine flip a coin will be repeated.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to be blind in this study, the pharmacist will put the medicines of groups A and B in the same-shape (uniform) packages and the prescription will be placed inside each package. The researcher will not know the type of medicines in these two groups. At first, the participants will be given the necessary explanations for participation and informed consent will be obtained. Blinding will be performed for the statistical analyzer. After completing the statistical analysis, the pharmacist will be asked about the type of medicines of groups A or B. The clinician will not know which medicine belongs to group A or B. Vaginal examination will be performed by a clinical caregiver and the bishop score will be determined and participants will be referred to another research colleague for medication. The medicine will be given to the participant according to the number of pregnancies and bishop score with the minimization method. In the next step, the clinical caregiver who does not know about the groups of the medicines will perform the examinations two and four hours later and will record it in the file. The other research colleague will complete the checklist according to the file.

Placebo
Not 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
رفسنجان
Province
Kerman
Postal code
77179335777
Approval date
2019-10-09, 1398/07/17
Ethics committee reference number
IR.RUMS.REC.1398.122

Health conditions studied

1

Description of health condition studied

Nornal vaginal delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The mean of Bishop's score

Timepoint

Determination of Bishop score before induction, two and four hours after induction

Method of measurement

The Bishop score table, which has five criteria including dilatation, effacement, fetal head station, softness, and position of the cervix during a vaginal examination. for scoring each of the first three criteria, take a score of 3-0, and each of the next two criteria, take a score of 2.-0.

Secondary outcomes

1

Description

The duration of the first stage of labor

Timepoint

From the onset of the active phase of labor to the complete opening of the cervix (measurements were taken every hour).

Method of measurement

Use checklist (written in the checklist every hour).

Intervention groups

1

Description

The first intervention group will receive two Prime rose capsules (oral,1000 mg, daily) made by Barich Essence Company, before induction.

Category

Treatment - Drugs

2

Description

The second intervention group will receive two Prime rose capsules (vaginal,1000 mg, daily) made by Barich Essence Company, before induction.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Nik Nafs Maternity center of Rafsanjan

Full name of responsible person

Leila Norouzian

Street address

21th Bostan Alley, Panzdah-e-Khordad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Alishamsizadeh

Street address

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

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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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mahdiyehsadat Hoseinipour

Position

Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Contact

Name of organization / entity

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Full name of responsible person

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Position

Totur

Latest degree

Master

Other areas of specialty/work

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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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable