Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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 stratums 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 stratums, and the next sample will belong to the class that has the least sum. If the samples are equal in stratums, 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
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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
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Position
Midwifery
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable