Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A Comparative investigation of the effect of oral castor oil capsules and evening primrose oil 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

Protocol summary

Study aim
Determination and Comparative investigation of the effect of oral castor oil capsules and evening primrose oil 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, triple-blind.

Settings and conduct
This study is a triple-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 six Gylax capsules (oral,1000 mg) at the time of induction. The location of this study is NickNafs Rafsanjan maternity hospital.

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

Intervention groups
The first intervention group will receive two Prime rose capsules (oral,1000 mg, daily) and the second intervention group will receive six Gylax capsules (oral,1000 mg) at the time of induction.

Main outcome variables
The mean Bishop score, Success of labor induction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190717044248N3**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **retrospective**

Last update: **2020-10-15, 1399/07/24**
Update count: **0**

Registration date
2020-10-15, 1399/07/24

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-11-11, 1398/08/20
Expected recruitment end date
2020-08-10, 1399/05/20
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative investigation of the effect of oral castor oil capsules and evening primrose oil 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

Public title

A Comparative investigation of the effect of oral castor oil capsules and evening primrose oil 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 delivery 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

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

- Participant
- 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)

Triple 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, but the participants will not know in which group (castor oil or evening primrose oil) they will be placed. The medicine will be given to participants as groups A or B. 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

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2019-11-08, 1398/08/17

Ethics committee reference number

IR.RUMS.REC.1398.121

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 six Gylax capsules (oral,1000 mg) at the time of induction made by Barich Essence Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nik Nafs maternity center of Rafsanjan

Full name of responsible person

Leila Norouzian

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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

Ali Shamsizadeh

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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
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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 informations
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