

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

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

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

Street address

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

City

Rafsanjan

Province

Kerman

Postal code

7715764581

Phone

+98 34 3422 5494

Email

azamfateh65@gmail.com

Web page address

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

Web page address

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

Street address

No. 37, 27th Alley, Mostafa Khomeini Ave., Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7714646737

Phone

+98 34 3422 0393

Email

shirinhoseinipour@yahoo.com

Web page address**Postal code**

7718145056

Phone

+98 34 3425 5900

Email

saghafiz@yahoo.com

Web page address**Person responsible for updating data****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 Ave

City

Rafsajan

Province

Kerman

Postal code

7718796755

Phone

+98 34 3425 5900

Email

Saghafiz@yahoo.com

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

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