Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

A comparative study on the effect of various doses of castor oil capsule (Gelax) on bishap score and some prenatal outcomes in nulliparous women refer to Niknafs Rafsanjan maternity hospital in

Protocol summary

Study aim
Determining the mean Bishop's score and some delivery outcomes between intervention and control groups

Design
Randomized Clinical Trial with two intervention groups and one control group; Three blindsides; Parallel groups. Randomization is done with a random numbers table.

Settings and conduct
In this randomized clinical trial, the statistical population Includes all nulliparous pregnant women. The sample size based on the statistical formula is thirty people in each group. The sampling is done by using the random numbers table. The study will include two intervention groups and one control group and it is triple-blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to normal vaginal delivery Selection of Niknafs Maternity Center of Rafsanjan as the place of delivery Mother age: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 Gelax Sensitivity to Gelax capsules Known history of psychological disorders Delivery complications such as polyhydramnios, oligohydramnios, preeclampsia, eclampsia, vaginal bleeding History of having confirmed psychological disorders

Intervention groups
The intervention group consumes 6 Gelax capsules contains one gram of castor oil daily. The second intervention group consumes 3 Gelax capsules contains one gram of castor oil daily. The control group consumes three Placebo capsules "similar to Gelax capsules" and containing one gram of sunflower oil

Main outcome variables
Bishop's score and some delivery outcomes such as; The length of the first stage of delivery; The length of the second stage of childbirth; Frequency of NVD; Instrumental delivery; Meconium; The need to induction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190717044248N1**
Registration date: **2020-06-29, 1399/04/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-29, 1399/04/09**
Update count: **0**

Registration date
2020-06-29, 1399/04/09

Registrant information

Name
Zahra Saghafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-05, 1398/10/15

Expected recruitment end date
2020-09-13, 1399/06/23

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of various doses of castor oil capsule (Gelax) on bishap score and some prenatal outcomes in nulliparous women refer to Niknafs Rafsanjan maternity hospital in

Public title

The effect of different doses of castor oil capsule (Gelax) on Bishop's score and some delivery outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inform consent for participant in the study Willingness to normal vaginal delivery Selection of Niknafs Maternity Center of Rafsanjan as the place of 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 Gelax Sensitivity to Gelax capsules 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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling; Random numbers table First, four centers from eight comprehensive health-care services centers in Rafsanjan will be selected as research units by a simple random method. Then, through the SIB system, the list of nulliparous pregnant women will be determined and will call with them, and among them who have inclusion criteria and willing to participate in the study will be determined as the final list. Then people will be classified into two intervention groups and one control group (A or B or C) based on the random numbers table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding, the pharmacist is 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 does not know about the content of packages (medicine or placebo). The medicine is also 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. At first, participants are justified about the study, and informed consent will be taken, but they are unaware of the content of packages (medicine or placebo). The clinical caregiver is also unaware of which A_B_C group contains each medicine. The researcher re-evaluated the 35-week pregnant mothers who have inclusion criteria and at 37 weeks for obtaining castor oil referred them to the distributor of Gelax packages, who were unaware of the contents of the A-B-C packages and according to random number table, one of the ABC groups is assigned to each participant. Another subcontractor is following up on the medical use plan of participants, and after the delivery, the other coworker will write the items research variables on the checklist based on the contents of the delivery file medical history. After completing 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.1398.050

Health conditions studied

1

Description of health condition studied
Bishop's score, Maternal and Neonatal outcomes
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

1

Description
Comparomisation the frequency of spontaneous labor onset
Timepoint
Delivery duration
Method of measurement
Using checklist

2

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
Method of measurement
Checklist

Intervention groups

1

Description
The first intervention group of use Six Gelax capsules contains one gram or one thousand milligrams of castor oil, made by Barich Essence Company, which they consume from noon to noon ant starts from 38 weeks to delivery time. If a person forgets to consume for two days, it will be removed from the study.The reason for using Gelax instead of castor oil is its better taste, which is better for eating.
Category
Treatment - Drugs

2

Description
The second intervention group of use three Gelax capsules contains one gram or one thousand milligrams of castor oil, made by Barich Essence Company, which they consume from noon to noon ant starts from 38 weeks to delivery time. If a person forgets to consume for two days, it will be removed from the study.The reason for using Gelax instead of castor oil is its better taste, which is better for eating.
Category
Treatment - Drugs

3

Description
The control group of use three Gelax capsules contains one gram or one thousand milligrams of sunflower oil, made by Barich Essence Company, which they consume from noon to noon ant starts from 38 weeks to delivery time. If a person forgets to consume for two days, it will be removed from the study.The reason for using Gelax instead of castor oil is its better taste, which is better for eating.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Niknafs Maternity Center of Rafsanjan
Full name of responsible person
Esmat Javadi
Street address
No. 4, 7th Alley, South Panzdah-e-Khordad Ave. Kamalabad
City
Rafsanjan
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Kerman
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7716765965
Phone
+98 34 3425 9030
Email
449@gmail.com

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 Rafsanjan University of Medical Sciences, Imam Ali Blvd
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7718146890
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Email
vcrt@rums.ac.ir
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
Azam Fatehzadeh
Position
Midwife
Latest degree
Bachelor
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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Zahra Saghafi
Position
Tutor
Latest degree
Master
Other areas of specialty/work
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Province
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Email
Saghafiz@yahoo.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
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