Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation The Effect of flaxseed powder use on the cervix ripening, initation and outcom of labor in primiparous women

Protocol summary

Study aim
The Effect of flaxseed powder use on the cervix ripening, initation and outcom of labor in primiparous women

Design
Randomised, Intervention and control group, simple randomised, The sample size 120 persons

Settings and conduct
In This study 120 qualify primiparous women that referring to an midwifery Office and their delivery will be done in niknafs maternity hospital will divided into intervention and control groups then from 37 weeks of pregnancy up to the time of childbirth intervention group will given 10 gr flax seed powder daily then cervical ripening and outcome of labor and delivery will be compared.

Participants/Inclusion and exclusion criteria
Iranian ethic, Primiparous, BMI less than 30, Gestational age less than 37 weeks, The lack of acute and chronic disease, Singleton pregnancy, Cephalic presentation, The lack of pregnancy complications, Written consent for cooperation, The lack of vaginal delivery conterandication, Not to use other ways to facilitate delivery

Intervention groups
This study is a randomized clinical trial, that 120 qualify primiparous women that will referring to an midwifery Office participated in. Samples will randomly divided into intervention and control groups. 28 package (each package 10 gr) of Flax seed powder will be given to each person of Intervention group and then will ask them fasting every morning a package of flax seed powder in a glass of lukewarm water from 37 weeks of pregnancy up to the time of childbirth. In control group, will not done any intervention.Demographic and midwifery information will be recorded in a two-part form and the two groups will be compared in terms of the cervical ripening and outcome of labor and delivery.

Main outcome variables
Bishop score, Initation of labor, out com of delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170810035617N2**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date
2018-09-04, 1397/06/13

Registrant information

Name
pouran Allahbakhshi nasab

Name of organization / entity
Rafsanjan university of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 34 3428 0097

Email address
p.allahbakhshi96@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation The Effect of flaxseed powder use on the cervix ripening, initation and outcom of labor in primiparous women

Public title
Investigation the effect of flaxseed powder use on the cervix ripening, initation and outcom of labor
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian ethic Primiparous women BMI<30 Gestational age 37 weeks and more Lack of acute and chronic disease Single fetus Cephalic presentation Lack of pregnancy complications
Exclusion criteria:
Vaginal birth conterandications Use of other vaginal delivery Facilitated methods Lack of mother coorperation Forgetting more than 3 days to use of flax seed powder Manifestation any side effects wise flaxseed powder use
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomisation
Blinding (investigator's opinion)
Not blinded
Blinding description
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
Blvd emam Ali
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2018-05-15, 1397/02/25
Ethics committee reference number
IR.RUMS.REC.1397.053

Health conditions studied

1

Description of health condition studied
the cervix ripening, initation and outcom of labor
ICD-10 code
O62
ICD-10 code description
Abnormalities of forces of labour

Primary outcomes

1

Description
use of flax seed powder
Timepoint
From 37 weeks of gestational age up to delivery
Method of measurement
Fill out the questionnaire

Secondary outcomes

1

Description
Cervix ripening
Timepoint
Hospital admission
Method of measurement
Bishop score

2

Description
Initation of labor
Timepoint
Hospital admission
Method of measurement
Need to induction percentage

3

Description
Out com of delivery
Timepoint
Post partume
Method of measurement
Duration of first and second stage of labor, Fetal distress percentage, Meconium passing percentage, Mean apgar score, Amount of post partume bleeding

Intervention groups

1

Description
Intervention group: Use of flax seed powder (10 g) daily from 37 weeks of gestational age Up to the time of delivery.
Category
Rehabilitation

2

Description
Control group: Just routine prenatal care will be done
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Midwifery office
Full name of responsible person
Pouran Allahbakhshi Nasab
Street address
No 9, Esteghlal Ave, West Amir kabir Blvd
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7717135879
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Email
p_allahbakhshi@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr Ali SHamyzadeh
Street address
Blvd Emam Ali
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Postal code
7717933777
Phone
+98 34 3428 0038
Email
info@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
Pouran Allahbakhshi Nasab
Position
Faculty
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Nursing and Midvifery Faculty, Parastar Ave, Jomhoory Blvd
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data after non-identifiable share
When the data will become available and for how long
Access 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Just for scientific use
From where data/document is obtainable
Pouran allahbakhshi nasab 0098 9138911459 p_allahbakhshi@rums.ac.ir
What processes are involved for a request to access data/document
Affiliation Determine the cause of the data request Sending data
Comments