

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Investigation The Effect of flaxseed powder use on the cervix ripening, initiation and outcome of labor in primiparous women

#### Protocol summary

##### Study aim

The Effect of flaxseed powder use on the cervix ripening, initiation and outcome 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 ethnic, 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, Initiation of labor, outcome 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, initiation and outcom of labor in primiparous women

**Public title**

Investigation the effect of flaxseed powder use on the cervix ripening, initiation 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 conterindications Use of other vaginal delivery Facilitated methods Lack of mother cooperation 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**

Bldv 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, initiation 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 appgar 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

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7717135879

#### Phone

+98 34 3435 1186

#### 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

Bldv Emam Ali

#### City

Rafsanjan

#### Province

Kerman

#### 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 Midwifery Faculty, Parastar Ave,  
Jomhoory Blvd

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7718796755

#### Phone

+98 34 3425 5900

#### Email

n.m.p@rums.ac.i

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Rafsanjan University of Medical Sciences

#### Full name of responsible person

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#### Position

Faculty

#### Latest degree

Master

#### Other areas of specialty/work

Midwifery

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n.m.p@rums.ac.ir

## Person responsible for updating data

### 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**  
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**Province**  
Kerman  
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**Fax**

+98 34 3425 8497

**Email**  
n.m.p@rums.ac.ir

## 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