

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative investigation of the effect of Fenugreek seed - flax seed and soy on the severity of depression at menopause

#### Protocol summary

##### Summary

The goal of research is comparison of the effect of fenugreek seed, Flaxseed and soy on menopausal depression. A prospective randomize control trial double blind(cases and sampler will be blind) will conduct on 120 women in menopause age that will assign to equal four groups : Fenugreek seed group (6g daily ), Flaxseed group (25 g daily ) , Soy group ( 25 g daily ) and sorbitol group (25 g daily ) for 8 weeks consequently. Score of depression will determine and analyzed in initial time of study and eight weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110262545N2**  
Registration date: **2012-04-18, 1391/01/30**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-04-18, 1391/01/30

##### Registrant information

##### Name

Naimeh Akbaritorkestani

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1417 3500

##### Email address

n.akbary@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research Arak University of Medical Sciences.

##### Expected recruitment start date

2009-09-16, 1388/06/25

##### Expected recruitment end date

2011-09-23, 1390/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative investigation of the effect of Fenugreek seed - flax seed and soy on the severity of depression at menopause

##### Public title

Comparative investigation of the effect of Fenugreek seed - flax seed and soy on the severity of depression at menopause

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: amenorrhea during the previous 12 months; with reporting menopausal depression; normal blood pressure; without use of estrogen and progesterone; without use anti depressant and anti anxiety drugs during the previous 6 months; without use of anticoagulants and NSAIDs for example ibuprofen; with out history of asthma and allergy. Exclusion criteria:Incorrect use of herbal plants; home change; skin irritation .

##### Age

From **45 years** old to **55 years** old

##### Gender

Female

##### Phase

4

## Groups that have been masked

No information

## Sample size

Target sample size: 120

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Arak University of Medical Sciences

##### Street address

Arak University of Medical Sciences, Sardasht, Arak, Iran.

##### City

Arak

##### Postal code

3848176941

#### Approval date

2009-09-16, 1388/06/25

#### Ethics committee reference number

88-65-8

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F32.0

#### ICD-10 code description

Depressive episode

## Primary outcomes

### 1

#### Description

Depression score

#### Timepoint

before intervention and two months after

#### Method of measurement

Beck depression questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Participants in first group by 6 grams of Fenugreek daily for 8 consecutive weeks, every day will be taken orally

#### Category

Treatment - Drugs

### 2

#### Description

Participants in second group by 25 grams of flaxseed daily for 8 consecutive weeks, every day will be taken orally

#### Category

Treatment - Drugs

### 3

#### Description

Participants in third groups by 25 grams of Soy daily for 8 consecutive weeks, every day will be taken orally

#### Category

Treatment - Drugs

### 4

#### Description

Participants in Control group by 25 grams of Sorbitol daily for 8 consecutive weeks, every day will be taken orally .

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Arak Taleghani hospital clinic

##### Full name of responsible person

Naimeh Akbari Torkestani

##### Street address

Taleghani hospital, Emam Khomeini street, Arak, Iran

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research Arak University of

Medical Sciences.

**Full name of responsible person**

Dr Said Changizi Ashtiyani

**Street address**

Arak University of Medical Sciences, Sardasht, Arak, Iran.

**City**

Arak

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research Arak University of Medical Sciences.

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Naimeh Akbaritorkestani

**Position**

Lecturer, M.Sc in Midwifery, Arak University of Medical Sciences

**Other areas of specialty/work**

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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)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*