

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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Email

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Web page address

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