

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of the effect of fenugreek seed, Flaxseed and soy on hot flashes menopause.

Protocol summary

Summary

Background: Hot flash is most common of menopausal women, that destroys sleep quality and decrease ability of prevail over stress and after days difficult. one of the complement therapies for it is phytoestrogens that rich sources of them find in Iran abundantly that are affordable and reasonable are Fenugreek seed, flaxseed and soy. The goal of research is comparison of the effect of fenugreek seed, Flaxseed and soy on menopausal hot flashes. Material and Methods: A prospective randomize control trial 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 Wheat group (25 g daily) for 4 weeks consequently. Women with amenorrhea during the previous 12 months with reporting menopausal hot flash , normal blood pressure without use of estrogen and progesterone, anti depressant and anti anxiety drugs during the previous 6 months as well as with out use of anticoagulants and NSAIDs for example ibuprofen and with out history of asthma and allergy will include in the research. Women with incorrect use of herbal plants, home change and skin irritation will exclude from study. Hot flash frequency and intensity will determine and analyzed in initial time of study, fourth and eight weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807122545N1**

Registration date: **2011-07-24, 1390/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

Name

Naimeh Akbaritorkestani

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences.

Expected recruitment start date

2008-07-20, 1387/04/30

Expected recruitment end date

2010-07-21, 1389/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of fenugreek seed, Flaxseed and soy on hot flashes menopause.

Public title

The comparison of the effect of fenugreek seed, Flaxseed and soy on hot flashes menopause.

Purpose

Treatment

Inclusion/Exclusion criteria

Women with amenorrhea during the previous 12 months with reporting menopausal hot flash , normal blood pressure without use of estrogen and progesterone, anti

depressant and anti anxiety drugs during the previous 6 months as well as with out use of anticoagulants and NSAIDs for example ibuprofen and with out history of asthma and allergy will include in the research. Women with incorrect use of herbal plants, home change and skin irritation will exclude from study.

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

Gender
Female

Phase
N/A

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
this study is experimental enter 120 women (sample size estimate whit a=%5 b=%20 Sd=1/5 d=1) 24woman in every group that employee in every group 30 woman.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences, Arak , Iran .

Street address

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

City

Arak

Postal code

3848176941

Approval date

2008-05-09, 1387/02/20

Ethics committee reference number

276

Health conditions studied

1

Description of health condition studied

Menopausal hot flash

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

frequency of hot flash

Timepoint

Initial of intervention and 4 week and 8 weeks after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Intensity of hotflashes

Timepoint

initial of study,4 , 8 weeks after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Fenugreek seed group (6g daily) for 4 weeks consequently

Category

Treatment - Drugs

2

Description

Flaxseed group (25 g daily)for 4 weeks consequently.

Category

Treatment - Drugs

3

Description

Soy group (25 g daily)for 4 weeks consequently

Category

Treatment - Drugs

4

Description

Wheat group (25 g daily) for 4 weeks consequently

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak University of Medical Sciences, Arak, Iran.

Full name of responsible person

Naimeh Akbari Torkestani

Street address

Arak university of medical science, Sardasht, 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.

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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 , Arak , Iran .

Full name of responsible person

Naimeh Akbari Torkestani

Position

master degree of midwifery

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Position

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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