Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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 hotflashs

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 Mdical Sciences, Sardasht, Arak, Iran.

City
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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
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Position
master degree of midwifery

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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