

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The study on effects of anise abstract on relief and recurrence of menopausal hot flashes in health care centers affiliated to Shahid Beheshti Medical University

Protocol summary

Summary

The aim of the present study is to assess the effects of anise abstract on relief and recurrence of menopausal hot flashes in postmenopausal women in health care centers affiliated to Shahid Beheshti Medical University. A total of 72 postmenopausal women will be randomly assigned into intervention or control group to receive either 330 mg capsules of anise abstract or 330mg capsules of starch powder, 3 times a day for 4 weeks. The frequency and severity of hot flashes will be measured and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103284317N4**
Registration date: **2011-05-15, 1390/02/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-15, 1390/02/25

Registrant information

Name

Fatemeh Nahidi

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 982188202512

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Recruitment status

Recruitment complete

Funding source

The Pharmaceutical Sciences Research Center, Shahid Beheshti Medical Sciences University

Expected recruitment start date

2009-12-21, 1388/09/30

Expected recruitment end date

2010-09-21, 1389/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study on effects of anise abstract on relief and recurrence of menopausal hot flashes in health care centers affiliated to Shahid Beheshti Medical University

Public title

The effects of anise abstract on relief and recurrence of menopausal hot flashes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 45-60, history of amenorrhea at least 1 and at most 3 years prior to the study, experience of hot flashes, being literate or having a literate family member, married or widowed since one year prior to the study, not using food or herbal medicine content of phytoestrogens. There was not confirmed of diabetes, hyperthyroidism, hypothyroidism or any other diseases causing hot flash, undergoing hormone therapy, taking anticoagulant, anti depressive or anxiolytic drugs, hypersensitivity to anise, experiencing stressful events such as divorce, death of her husband, or death of her close family members during 6 months prior to the study

Exclusion criteria: The subjects were decided to use drug or hormone and herbals medicin to relieve hot flashes.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shaheed Beheshti University of Med Sciences

Street address

Shaheed Beheshti University of Medical Sciences and Health Services, Beside Taleghani Hospital, Evin, Tabnak St., Shaheed Chamran Avenue, Tehran, Iran

City

Tehran

Postal code

Approval date

2010-01-03, 1388/10/13

Ethics committee reference number

5695-114-01-87

Health conditions studied

1

Description of health condition studied

Hot flash

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Recurrence

Timepoint

Weekly

Method of measurement

Study data sheet

2

Description

Frequency of hot flash

Timepoint

Weekly from two weeks before intervention to four weeks after intervention

Method of measurement

Study data sheet

3

Description

Severity of hot flash

Timepoint

Weekly from two weeks before intervention to four weeks after intervention

Method of measurement

Study data sheet

Secondary outcomes

1

Description

Weight

Timepoint

Weekly

Method of measurement

Scale

Intervention groups

1

Description

Interventionl group will take capsules containing 330mg anise abstract for 8 weeks 3 times a day (morning, noon and night).

Category

Treatment - Drugs

2

Description

Control group will take placebo capsulescontaining 330mg starch with the same shape for 8 weeks 3 times a day (morning, noon and night).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers affiliated to Shahid Beheshti
Medical University

Full name of responsible person

Fatemeh Nahidi faculty member of Shaheed Beheshti
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmaceutical Sciences Research Center

Full name of responsible person

Farshad H. Shirazi

Street address

Pharmaceutical Sciences Research Center ,School of
Medicien, Below of Niyayesh,Avenue Valiasr

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical Sciences Research Center

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

shaheed Beheshti university of medical sciences

Full name of responsible person

Fatemeh Nahidi

Position

Faculty member of Shaheed Beheshti University of
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Other areas of specialty/work

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Position

Faculty member ,MSc in Midwifery and student of PhD
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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