

# 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

###### Email address

nahidi@sbmu.ac.ir

##### 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  
University of Medical Sciences ,MSc in Midwifery a

#### Street address

Health care centers affiliated to Shahid Beheshti  
Medical University

#### City

Tehran

Taleghani Hospital, Evin, Tabnak St., Shaheed  
Chamran Avenue, Tehran, Iran

#### City

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#### Postal code

#### Phone

+98 21 2243 9912

#### Fax

#### Email

nahidifateme@yahoo.com; nahidi@sbm.ac.ir

#### Web page address

## 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  
Medical Sciences ,MSc in Midwifery and student o

#### Other areas of specialty/work

#### Street address

Women's affairs Office, Shaheed Beheshti University  
of Medical Sciences and Health Services, Beside

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shaheed Beheshti University of Medical Sciences

#### Full name of responsible person

Fatemeh Nahidi

#### Position

Faculty member ,MSc in Midwifery and student of PhD  
in Health Education

#### Other areas of specialty/work

#### Street address

Women's affairs Office, Shaheed Beheshti University  
of Medical Sciences and Health Services, Beside  
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Chamran Avenue, Tehran, Iran

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nahidifateme@yahoo.com

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Shaheed Beheshti University of Medical Sciences

#### Full name of responsible person

Fatemeh Nahidi

#### Position

Faculty member ,MSc in Midwifery and student of PhD  
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#### City

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#### Fax

#### Email

nahidifateme@yahoo.com

**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*