

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The clinical trial of valeriana and placebo comparison on severity and frequency of hot flash in menopausal women

Protocol summary

Summary

Objective: this study assesses the effect of Valeriana on the intensity and frequency of hot flashing Design: triple-blind randomized clinical trial that will be conducted on 64 menopauses between 45-55 years in health center of Shohada in Hamadan city. They will be randomly assigned to intervention and control groups with regard to Allocation concealment (32 in intervention group and 32 in control group). Setting and conduct: the eligible women with hot flashing complaint who refer to health center of Shohada in 2015 will be enrolled. Inclusion criteria: (a) age of between 45-55; (b) elapse of at least one and at most 5 years after menopausal (c) using cigarette and alcohol; (d) no having physical or mental diseases; (e) no using relaxation techniques (f) no using hormonal or herbal therapies Exclusion criteria: (a) drug intolerance (b) not complete treatment duration intervention: The treatment will be administered for capsule sedamin contain 530 milligram Valeriana twice in day for 2 months and in control group placebo will be prescribed similar to Valeriana for 2 months. Main outcome measures: the two groups will be compared in terms of the hot flash severity and frequency by Cooperman Index before the intervention, 1 month after the intervention and 2 months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507206888N10**

Registration date: **2015-09-11, 1394/06/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-11, 1394/06/20

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

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Email address

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2015-12-31, 1394/10/10

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial of valeriana and placebo comparison on severity and frequency of hot flash in menopausal women

Public title

The effect of Valeriana on severity and frequency hot flashes in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of between 45-55; elapse of at least one and at most 5 years after menopausal; no using cigarette and alcohol; no having physical or mental

diseases; no using of relaxation techniques; no using of hormonal or herbal therapies Exclusion criteria: drug intolerance; not complete treatment duration

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: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Postal code

65178

Approval date

2015-04-11, 1394/01/22

Ethics committee reference number

UMSHA.REC.1394,7

Health conditions studied

1

Description of health condition studied

Hot flash

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes

1

Description

Hot flash severity

Timepoint

before the intervention, 1 month after intervention, 2 months after the intervention

Method of measurement

Cooperman Index

2

Description

hot flash frequency

Timepoint

before the intervention, 1 month after intervention, 2 months after the intervention

Method of measurement

Cooperman Index

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group: Sedamin will be prescribed in the form of Oral Capsule 530 mg, Twice in a day along two months. This drug Will be bought from Goldaroo Company in Iran.

Category

Treatment - Drugs

2

Description

In control group: placebo will be prescribed in the form of Oral Capsul contain 530 mg valeriana Twice in a day along two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Medical and Health Center

Full name of responsible person

Nahid Mohammadi, M.Sc. of Health, Instructor

Street address

No. 11, Takhti Street, Shohada Medical and Health Center, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Saied Bashirian

Street address

No. 307, Fahmideh Street, Hamadan University of Medical Sciences

City

Hamadan

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, Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

Other areas of specialty/work

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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