Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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

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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