Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Fennel and valerian extract on the menopause symptom in women reffered to Comprehensive Health Centers

Protocol summary

Study aim
The effect of Fennel and valerian extract on the menopause symptom

Design
Clinical trial with control group, with parallel groups, double blind, randomized

Settings and conduct
Participants are randomly assigned to the two groups of 38 recipients of capsule of fennel-Valerian extract and placebo group.This study will be conducted in Comprehensive Health Centers of Hamadan city. In this study, neither the researcher nor the menopausal women knows the contents of the package and double blinded will be performed. In intervention group, Capsule of Fennel-Valerian extract and in Control group, placebo will be prescribed Twice in a day along two months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 45-55, not using cigarette or alcohol, not having physical or mental diseases, not using of relaxation techniques, not using of hormonal or herbal therapies Exclusion criteria: not have

Intervention groups
Intervention group: Capsule of Fennel-Valerian extract will be prescribed in the form of Oral Capsule 500 mg, Twice in a day along two months. This drug Will be producted by Hamadan University of Medical Sciences. Control group: placebo will be prescribed in the form of Oral Capsule contain ỏf Starch 500 mg Twice in a day along two months. Placebo is made by Hamadan University of Medical Sciences.

Main outcome variables
Hot flash severity; Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180707040370N5**
Registration date: **2019-08-19, 1398/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-19, 1398/05/28**
Update count: **0**

Registration date
2019-08-19, 1398/05/28

Registrant information

Name
Ensiyeh Jenabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0496

Email address
e.jenabi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Fennel and valerian extract on the menopause symptom in women reffered to Comprehensive Health Centers

Public title
The effect of Fennel and valerian extract on the

menopause symptom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 45-55 not using cigarette or alcohol not having physical or mental diseases not using of relaxation techniques not using of hormonal or herbal therapies

Exclusion criteria:

not have

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly selected by (randbetween (1; 2)) command, in the Excel computer program that are assigned to the two groups of 38 recipients of capsule of fennel-Valerian extract and placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug packages are similar and were given to menopausal women by other person. This person does not inform about the package contents. therefore, neither the researcher nor the menopausal women knows the contents of the package and double blinding will be performed.

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

Hamadan University of Medical Sciences, Fahmiheh Street, Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.UMSHA.REC.1398.344

Health conditions studied

1

Description of health condition studied

Hot flash and sleep quality

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Hot flash severity

Timepoint

before intervention, immediately after intervention and and one month after intervention

Method of measurement

Cooperman Index

2

Description

Sleep quality

Timepoint

before intervention, immediately after intervention and and one month after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule of Fennel-Valerian extract will be prescribed in the form of Oral Capsule 500 mg, Twice in a day along two months. This drug Will be producted by Hamadan University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: placebo will be prescribed in the form of Oral Capsule contain ỏf Starch 500 mg Twice in a day along two months. The placebo is made in Hamadan University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Service Center of Shohada

Full name of responsible person
Ensiyeh Jenabi

Street address
Comprehensive Health Service Center of Shohada., Takhti Ave., Hamadan

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2

Recruitment center

Name of recruitment center
Comprehensive Health Service Center of Khezr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeid Bashirian

Street address
Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Av

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S_bashrian@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Hamedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Ensiyeh Jenabi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
A portion of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long
6 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Data analysis is permitted with the author's permission.

From where data/document is obtainable
Hamadan University of Medical Sciences

What processes are involved for a request to access data/document
6 months after of paper publish

Comments