

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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

Registration timing: **registered_while_recruiting**

Study aim

The effect of Fennel and valerian extract on the menopause symptom

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

Update count: **0**

Design

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

Registration date

2019-08-19, 1398/05/28

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.

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

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

Recruitment status

Recruitment complete

Funding source

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

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

Main outcome variables

Hot flash severity; Sleep quality

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040370N5**

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 one month after intervention

Method of measurement

Cooperman Index

2

Description

Sleep quality

Timepoint

before intervention, immediately after intervention 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 produced by Hamadan University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: placebo will be prescribed in the form of Oral Capsule contain of 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

City

Hamadan

Province

Hamadan

Postal code

6517838344

Phone

+98 81 3252 4321

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Shohada.health@yahoo.com

2

Recruitment center

Name of recruitment center

Comprehensive Health Service Center of Khezr

Full name of responsible person

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Comprehensive Health Service Center of Khezr., Khezr Ave., Hamadan

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6517838289

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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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6517838695

Phone

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Email

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

Contact

Name of organization / entity

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Ensiyeh Jenabi
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Latest degree
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Other areas of specialty/work
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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