

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of fennel, vitex and placebo oral products on menopausal problems in menopausal women : a double -blind randomized clinical trial

Protocol summary

Study aim

Comparison the effect of Fennel, Vitex and placebo oral products on menopausal problems: A double-blind randomized clinical trial 1

Design

A randomized double-blind, clinical trial with parallel control group, with six blocks, phase 3

Settings and conduct

The capsules will look similar to each other. The study location will be Menopausal clinic of Fatemeh Hospital belongs to Hamadan University of Medical Sciences. Researchers and menopausal women will be blinded.

Participants/Inclusion and exclusion criteria

1- Menopausal women 45-65 years old who have not menstruated for at least one year 2- Do not take another drug to treat menopausal problems 4- Complaining of any of the physical complications of menopause 5- Do not suffer from cardiovascular and liver diseases, Diabet, cancer 7- Not addicted to tobacco and alcohol

Intervention groups

Using the method of six random blocks, people will be randomly assigned to one of the three groups A, B, C. Participants in group A will be given the required number of Fennel capsules, participants in group B will be given a capsule containing Vitex, and those assigned to group c will be given a Placebo.

Main outcome variables

Hot flashes / night sweats Heart palpitations Sleep Disorders Muscle and joint pain Feeling depressed Being nervous Anxiety Forgetfulness

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20220417054567N1**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Mojgan Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of fennel, vitex and placebo oral products on menopausal problems in menopausal women : a double -blind randomized clinical trial

Public title

Comparison the effect of fennel and vitex

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Menopausal women 45-65 years who have not been menstruating for at least the past year Do not take any other medicine to treat menopausal problems

Complaints of any of the physical complications of menopause No cardiovascular and liver disease No history of breast or endometrial cancer in yourself or a first-degree family No addiction to smoking and alcohol Do not have diabetes Satisfaction to participate in the project

Exclusion criteria:

Allergy to prescribed drugs Do not take prescribed medications for at least a week

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **135**

More than 1 sample in each individual

Number of samples in each individual: **2**

Clinical signs and menopausal problems will be assessed twice at the beginning and end of the study.

Randomization (investigator's opinion)

Randomized

Randomization description

By the method of six random blocks, people will be randomly assigned to one of the three groups A, B, or C. For this purpose, six sheets of paper are prepared. The letter A (intervention with fennel) is written on two sheets, the letter B (intervention with vitex) is written on two sheets, and the letter C (control) is written on the other two sheets. The sheets are mixed together and selected by the researcher sequentially without replacement. This operation is repeated to the number of eligible patients and the group A, B, or C of each patient is recorded in front of the patient's visit and only with the knowledge of the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

Fennel, five-fingered, and placebo are prepared by the researcher in the form of similar capsules and will be given to the doctor. However, the patient's physician and the patient themselves will not know any of the contents of the labeled capsules. The doctor will be told to use capsule 1 for patient # 1. In the same way, all patients are numbered based on their turn and the capsule with the same number is used for them.

Placebo

Used

Assignment

Parallel

Other design features

both women and researchers are blinded

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Hamadan Medical Sciences University

Street address

Boulevard Shahid Fahmideh

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6517838678

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.UMSHA.REC.1401.035

Health conditions studied**1****Description of health condition studied**

Menopausal singe

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Improve menopausal symptoms

Timepoint

At the beginning of the study,4 and 8 weeks later

Method of measurement

Base on research sample

Secondary outcomes

empty

Intervention groups**1****Description**

Take fennel capsules containing one gram of fennel fruit once a day

Category

Treatment - Drugs

2**Description**

: Vitex Capsule containing VITEX AGNUS-CASTUS product in the amount of 4.8 - 3.2 mg and its standardization according to the composition of Ecobin

Category

Treatment - Drugs

3**Description**

Control group: placebo(starch capsule)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Menopause Clinic of Fatemeh Hospital, Hamadan

Full name of responsible person

Dr.Mehdi Biglarkhani,MD, PhD

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Web page address<https://www.umsha.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Web page address<https://www.umsha.ac.ir/>**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

Dr.Mehdi Biglarkhani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available