Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of fennel, vitex and placebo oral products on menopausal problems in menopaused 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 Fatemieh Hospital belongs to Hamadan University of Medical Sciences. Researchers and menopaused 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

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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 menopaused 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
City
Hamadan
Province
Hamadan
Postal code
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 Fatemieh Hospital, Hamadan
Full name of responsible person
Dr.Mehdi Biglarkhani,MD, PhD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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