Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Hot Flash Severity, Frequency, and Duration Before and After Administration of Fenelis Herbal Product in Menopausal Women

Protocol summary

Study aim

To evaluate the effects of the Fenelis herbal formulation (a combination of Melissa officinalis, Foeniculum vulgare, and Golghand) on the severity, frequency, and duration of hot flashes in postmenopausal women.

Design

Single-arm, before-after, triple-blind, phase 2 clinical trial conducted on 20 participants (15 completers) in selected healthcare centers in Isfahan, Iran. Random allocation was not applicable due to the single-arm design.

Settings and conduct

The trial was conducted in selected healthcare centers in Isfahan Province, Iran, from March 2020 to March 2021. Participants recorded hot flash events for one week at baseline, followed by three weeks of Fenelis capsule administration. Participants, care providers, and outcome assessors were blinded to the study hypotheses and expected outcomes. Data were coded prior to statistical analysis to blind the data analyst.

Participants/Inclusion and exclusion criteria

Menopausal women aged 45 to 64 years with hot flash complaints were included. Women with a history of hormone therapy in the past 3 months, use of herbal supplements for menopausal symptoms, surgical menopause, known allergy to Fenelis components, or serious chronic disease were excluded.

Intervention groups

Intervention group: Participants received Fenelis herbal capsules (containing Melissa officinalis, Foeniculum vulgare, and Golghand) for three weeks following one week of baseline hot flash recording.

Main outcome variables

Hot flash frequency (daily count); hot flash severity (mild, moderate, severe, very severe); hot flash duration; quality of life score (Greene scale); anxiety and depression score (Greene scale).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260623069929N1**
Registration date: **2026-07-10, 1405/04/19**
Registration timing: **retrospective**

Last update: **2026-07-10, 1405/04/19**
Update count: **0**

Registration date

2026-07-10, 1405/04/19

Registrant information

Name

Seyed Mohammadhassan Nazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2021-03-21, 1400/01/01

Trial completion date

2021-04-11, 1400/01/22

Scientific title

Comparison of Hot Flash Severity, Frequency, and Duration Before and After Administration of Fenelis Herbal Product in Menopausal Women

Public title
Fenelis herbal product for hot flashes in menopausal women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 45 to 64 years Natural menopause (at least 12 months of amenorrhea) Experiencing hot flashes Ability to read and write in Persian Willingness to participate and sign informed consent
Exclusion criteria:
History of hormone replacement therapy in the past 3 months Use of herbal or complementary medicine for menopausal symptoms in the past month Surgical menopause (oophorectomy) Known allergy to any component of Fenelis product Serious chronic disease (cardiovascular, hepatic, renal, or malignancy) Current use of medications affecting vasomotor symptoms Psychiatric disorders under treatment
Age
From **45 years** old to **64 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **20**
Actual sample size reached: **15**
More than 1 sample in each individual
Actual sample size in each individual: **1**
Each participant contributed one sample to the study.
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study was designed as a triple-blind clinical trial. Participants were unaware of the exact composition and anticipated effects of the Fenelis formulation to minimize performance bias. The healthcare personnel responsible for administering the capsules were blinded to the study hypotheses and expected outcomes. Outcome assessors who evaluated the severity, frequency, and duration of hot flashes, as well as the quality of life, anxiety, and depression questionnaires, were also blinded to the study objectives. Prior to statistical analysis, all data were coded, and the data analyst worked exclusively with the coded dataset.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Islamic Azad University, Najafabad Branch
Street address
University Boulevard, Najafabad, Isfahan, Iran.
City
Najafabad
Province
Isfehan
Postal code
8514143131
Approval date
2020-12-31, 1399/10/11
Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1400.056

Health conditions studied

1

Description of health condition studied
Menopausal hot flashes (vasomotor symptoms associated with menopause)
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Daily frequency of hot flashes
Timepoint
At baseline (before intervention), and at the end of week 1, week 2, and week 3 of intervention.
Method of measurement
Daily hot flash diary completed by participants.

2

Description
Severity of hot flashes
Timepoint
At baseline (before intervention), and at the end of week 1, week 2, and week 3 of intervention.
Method of measurement
Four-point severity scale classified as mild, moderate, severe, and very severe, recorded in a daily hot flash

diary.

3

Description
Duration of hot flashes
Timepoint
At baseline (before intervention), and at the end of week 1, week 2, and week 3 of intervention.
Method of measurement
Daily hot flash diary completed by participants.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants assigned to the intervention group received Fenelis herbal capsules. Fenelis is a combined phytoestrogenic herbal formulation containing Melissa officinalis (lemon balm), Foeniculum vulgare (fennel), and Golghand (rose petal preserve), developed according to the principles of Traditional Persian Medicine. Following a one-week baseline symptom recording period, participants orally consumed the capsules for three consecutive weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Najafabad Branch
Full name of responsible person
Seyed Mohammadhassan Nazeri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Islamic Azad University, Najafabad Branch
Full name of responsible person
Iman Sadeghkhani
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Grant name
Thesis for MD
Grant code / Reference number
162288275
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Islamic Azad University, Najafabad Branch
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
Islamic Azad University
Full name of responsible person
Seyed Mohammadhassan Nazeri
Position
MD-Ph.D.
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

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Associate professor

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Person responsible for updating data

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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
Yes - There is 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
No - There is not 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
Not applicable

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

Title and more details about the data/document
Study protocol of the clinical trial evaluating the effect of Fenelis herbal product on menopausal hot flashes

When the data will become available and for how long
Starting 6 months after publication of the study results, available for a period of 3 years

To whom data/document is available
Available to researchers affiliated with academic and research institutions

Under which criteria data/document could be used
For non-commercial academic research purposes only. Requests will be reviewed by the principal investigator.

From where data/document is obtainable
Requests should be submitted via email to the principal investigator at Islamic Azad University, Najafabad Branch, University Boulevard, Najafabad, Isfahan, Iran.

What processes are involved for a request to access data/document
Applicants should submit a written request including the purpose of use and institutional affiliation. Requests will be reviewed within 4 weeks of receipt.

Comments