

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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		Single
Public title Fenelis herbal product for hot flashes in menopausal women		Other design features
Purpose Treatment		Secondary Ids empty
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		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 Isfahan Postal code 8514143131 Approval date 2020-12-31, 1399/10/11 Ethics committee reference number IR.IAU.NAJAFABAD.REC.1400.056
Age From 45 years old to 64 years old		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
Gender Female		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.
Phase 2		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
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		

diary.

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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

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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

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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

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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