# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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.
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**Province**
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**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
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## Sponsors / Funding sources

**1**

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Vice Chancellor for Research, Islamic Azad University, Najafabad Branch
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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**
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MD-Ph.D.
**Latest degree**
Medical doctor
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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**