# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

## Protocol summary

**Study aim**
Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

**Design**
Before and after pilot clinical trial, Phase 3, on 45 patients, without blinding and control group

**Settings and conduct**
After recording the information of patients admitting to Shohadaye Tajrish Hospital, they complete the form of the number and severity of hot flashes episodes on a daily basis for a week, and at the end of the week, the number and severity of hot flashes episodes as well as the number of days without hot flashes episodes are calculated and considered as baseline values before the intervention. Then, patients use 5 cc of chicory and fumitory herbal products daily, fasting in the morning and at night for 4 weeks, and also complete the the form. After 4 weeks, the effect of the herbal product on the number and severity of hot flashes is analyzed.

**Participants/Inclusion and exclusion criteria**
Menopause (absence of menstruation during the last 12 months); Complaints of hot flashes; No use of anticoagulant medications; No history of any cardiovascular disease, diabetes, hypertension, neurological disease or cancer; Do not use cupping, acupuncture, medication, especially hormonal drugs, and not treating hot flashes with other methods during the last month; Do not use antidepressants in the last 4 weeks (venlafaxine, bupropion, fluoxetine, paroxetine, citalopram, sertraline); FSH > 40 IU/L; Having the consent to start and continue the study

**Intervention groups**
A group of chicory and fumitory product consumer

**Main outcome variables**
Improvement of hot flashes severity in postmenopausal women

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160722029027N13**
Registration date: **2022-07-05, 1401/04/14**
Registration timing: **retrospective**

Last update: **2022-07-05, 1401/04/14**
Update count: **0**

**Registration date**
2022-07-05, 1401/04/14

**Registrant information**

**Name**
Leila Nazari

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2271 8000

**Email address**
nazari@sbmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-03-21, 1400/01/01

**Expected recruitment end date**
2021-11-21, 1400/08/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

**Public title**
Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Menopause (absence of menstruation during the last 12 months) Complaints of hot flashes FSH > 40 IU/L Having the consent to start and continue the study
**Exclusion criteria:**
History of any cardiovascular disease, diabetes, hypertension, neurological disease, cancer of the breast, ovary, uterus, or hormone-sensitive diseases such as endometriosis or uterine fibroids Use antidepressants in the last 4 weeks (venlafaxine, bupropion, fluoxetine, paroxetine, citalopram, sertraline) Use of anti-anxiety drugs, gabapentin, pregabalin, clonidine, aspirin, vitamin E, omega 3, phytoestrogen supplements and high phytoestrogen diet during the intervention Use of acupuncture and complementary medicine (hypnosis, psychosomatic therapies) during the intervention Use cupping, acupuncture, medication, especially hormonal drugs, and not treating hot flashes with other methods during the last month Use of anticoagulant medications Taking herbal medicine or special diet to treat hot flashes Drug allergy to chicory and fumitory products
**Age**
From **45 years** old to **60 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **45**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
School of Medicine - Shahid Beheshti University of Medical Sciences
**Street address**
Velenjak, Yaman St, Chamran highway, Shahid Beheshti University of Medical Sciences
**City**
Tehran
**Province**
Tehran
**Postal code**
1983969411
**Approval date**
2019-07-30, 1398/05/08
**Ethics committee reference number**
IR.SBMU.MSP.REC.1398.460

## Health conditions studied

**1**

**Description of health condition studied**
Menopausal and climacteric symptoms
**ICD-10 code**
N95.1
**ICD-10 code description**
Menopausal and female climacteric states

## Primary outcomes

**1**

**Description**
Number and severity of hot flashes episode
**Timepoint**
Daily
**Method of measurement**
Recording the number and severity of hot flashes episodes (Green Climactric Scale) by patient

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Use of 5 cc of chicory and fumitory products, in the morning and at night, for 4 weeks
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shohadaye Tajrish hospital

**Full name of responsible person**
Dr. Leila Nazari
**Street address**
Tajrish square
**City**
Teharn
**Province**
Tehran
**Postal code**
1989934148
**Phone**
+98 21 25719
**Email**
nazari@sbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
**Street address**
Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1985717413
**Phone**
+98 31 5533 4611
**Email**
nazari@sbmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice Chancellor for research of Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Leila Nazari
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Velenjak, Yaman st, Chamran highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1983969411
**Phone**
+98 21 2271 8000
**Fax**
+98 21 2274 1171
**Email**
nazari@sbmu.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Leila Nazari
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Taleghani hospital, Yaman st, Velenjak, Chamran highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1983969411
**Phone**
+98 21 2243 2558
**Fax**
**Email**
nazari@sbmu.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Leila Nazari
**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Street address**

Taleghani hospital, Yaman st, Velenjak, Chamran highway

**City**

Tehran

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**Postal code**

1983969411

**Phone**

+98 21 2243 2558

**Fax**

**Email**

nazari@sbmu.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

General patient data

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available