Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

the effect of Heracleum persicum hydroalcoholic extract on hot flashes in menopausal women

Protocol summary

Study aim
Determining the effect of "Hydroalcoholic Extract of Heracleum parsicum" on hot flashes in menopausal women

Design
Triple blind randomized clinical trial with two intervention and control groups on 80 menopausal women. Randomization is by randomly assigned blocking (blocks with size four).

Settings and conduct
Participants were selected from menopausal women with symptoms of hot flashes referred to Mashhad health centers and after completing the written consent form, personal details and menstruation, daily hot flashes registration form and night sweats registration form for daily hot flashes and night sweats registration for up to 4 weeks. To confirm that a person has hot flashes, people are screened for 2 weeks and if they have 5 moderate or severe hot flashes per day, they are included in the study.Then offer the same medicine capsules to the two groups to take daily for 4 weeks Data before the intervention and data 2 and 4 weeks after the intervention are analyzed with SPSS software version 16.Blinding involves the researcher, the outcome evaluator, the participant, and the data analyst

Participants/Inclusion and exclusion criteria
Inclusion criteria: At least 12 months after the last normal menstruation or FSH more than 40 and a maximum of ten year after the last normal menstruation, healthy Pap smear , do not use agents that reduce hot flashes, no chronic diseases Exclusion criteria: Major changes in diet and physical activity pattern, use of measures to reduce hot flashes during the study, not filling out the hot flashes questionnaire for 3 days or more One week, not taking the drug for 2 days or more

Intervention groups
Individuals are randomly divided into two treatment groups. The control group received Avisel 500 mg capsules and the intervention group received 500 mg Golpar capsules once a day for 4 weeks.

Main outcome variables
Duration, severity and frequency of hot flashes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220102053592N1**
Registration date: **2022-06-18, 1401/03/28**
Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**
Update count: **0**

Registration date
2022-06-18, 1401/03/28

Registrant information

Name
Seyedeh Faezeh Shajiee Jazin

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-01, 1401/04/10

Expected recruitment end date
2022-09-01, 1401/06/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of Heracleum persicum hydroalcoholic extract on hot flashes in menopausal women

Public title

the effect of Heracleum persicumon hot flashes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian and resident of Mashhad Literacy for reading and writing Phone number to call At least 12 months after the last normal menstruation or FSH> 40 and a maximum of one year after the last normal menstruation Healthy Pap smear: if the Pap smear is Liquid based from 5 years ago and the traditional Pap smear is from 3 years ago Complaints of hot flashes: on average during 2 weeks of screening, having moderate or severe hot flashes 5 or more times a day Not receiving estrogen or progesterone for the past three months No spotting in the past year Do not use tobacco (cigarettes, hookah and drugs) and alcohol No tragic events in life in the last 6 months: Death of spouse, children or close family members, severe illness of family members, major change in employment and life, dismissal or unemployment of self or spouse Severe family dispute or divorce Do not use medications to reduce the symptoms of hot flashes for the past 1 month: Hormonal contraceptives, venlafaxine, paroxytin, fluoxetine, gabapentin, clonidine, vitamin E supplements, bromocriptine, oral naloxone, veralipride, yoga, acupuncture, citalopram, sertraline, pre-gabapentin, relaxation techniques No chronic diseases: Cardiovascular, liver disorders, skin diseases, thyroid disorders Lack of sensitivity to Heracleum persicum: Includes any changes and skin allergies and sensitivity to sunlight Do not use medicinal plants containing phytoestrogens: including soybeans, flaxseed, licorice, fenugreek, fennel, hops, sage, red clover, black cohosh

Exclusion criteria:

Major changes in nutrition and physical activity patterns: Starting exercise programs Use of medicinal plants containing phytoestrogens during the study: including soybeans, flaxseed, licorice, fenugreek, fennel, hops, sage, red clover, black cohosh use medications to reduce the symptoms of hot flashes for the past 1 month: Hormonal contraceptives, venlafaxine, paroxytin, fluoxetine, gabapentin, clonidine, vitamin E supplements, bromocriptine, oral naloxone, veralipride, yoga, acupuncture, citalopram, sertraline, pre-gabapentin, relaxation techniques Do not fill out the hot flush questionnaire for 3 days or more in a week Do not take the drug for 2 days or more Occurrence of symptoms of allergy to heracleum persicum during the study: includes any changes and skin sensitivity and sensitivity to sunlight, including any changes and skin sensitivity and sensitivity to sunlight

Age

From **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block stratified random allocation is used. In the first stage, based on the BMI index, the samples are placed in three classes: BMI≥30, BMI = 25-29.9 and BMI <25. Then, inside the classes, the samples are assigned to research groups A or B by randomly allocating blocks with quadruple blocks using PASS statistical software. To hide the allocation, sealed envelopes are numbered in order. This form is opened according to the order of entry of eligible participants to study the relevant envelope and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is triple blind; This means that the participant, researcher and outcome evaluator and data analyst are unaware of the allocation of study groups and the same capsules in terms of color, odor and shape for both groups (drug and placebo) in the same box with a code label. (A and B coded by the pharmacologist) are used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

University Street, Mashhad, Khrasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.002

Health conditions studied

1

Description of health condition studied

Hot flashes

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Duration of hot flashes

Timepoint

At the beginning of the study and 2 and 4 weeks after the intervention

Method of measurement

Daily hot flush registration form

2

Description

Intensity of hot flashes

Timepoint

At the beginning of the study and 2 and 4 weeks after the intervention

Method of measurement

Daily hot flush registration form

3

Description

Frequent flushing

Timepoint

At the beginning of the study and 2 and 4 weeks after the intervention

Method of measurement

Daily hot flush registration form

Secondary outcomes

1

Description

Intensity of night sweats

Timepoint

At the beginning of the study and 2 and 4 weeks after the intervention

Method of measurement

Night sweat registration form

2

Description

Frequent night sweats

Timepoint

At the beginning of the study and 2 and 4 weeks after the intervention

Method of measurement

Night sweat registration form

Intervention groups

1

Description

Intervention group: To the intervention group, capsules containing 500 mg of hydroalcoholic extract of Angelica baccarat Herbarium E1259-FUMH, prepared in the laboratory of Mashhad School of Traditional Medicine, are given one orally daily for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: To the control group, capsules containing 500 mg of oral Avisel powder prepared in the laboratory of Mashhad School of Traditional Medicine will be given as one drop orally daily for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad health centers

Full name of responsible person

Faezeh Shajieej

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Sponsors / Funding sources

1

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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Faezeh Shajieej
Position
Masters student
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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

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