Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of aerial organs portulaca oleracea syrup on menopausal hot flashes

Protocol summary

Study aim
Determining and comparing the severity and duration of hot flashes of aqueous extract of portulaca oleracea syrup and placebo

Design
A double-blind randomized controlled clinical trial was performed on 70 women over the age of 45 years. Randomization was performed using random selection software.

Settings and conduct
Patients referred to the health center affiliated with Ilam University of Medical Sciences will enter the study if the steps are approved and the inclusion criteria are included in the plan. The study is a two-way blind study in which the patient and the researcher are blind. Patients are asked to complete daily records of the number and severity of hot flashes and night sweats for 2 weeks. The patient consumes 3 tablespoons equivalent to 10 cc of syrup daily for 3 months in the morning, noon and night.

Participants/Inclusion and exclusion criteria
Women over 45 years of age complain of vasomotor symptoms and want treatment Inclusion criteria: stop menstruation, have daily hot flashes, serum FSH more than 40 international units and serum LH more than 30 international units according to laboratory report No entry conditions: Known physical and mental illnesses, use of hormone therapy, anticoagulants, sedatives, antidepressants, anticonvulsants, alpha-adrenergic agonists, and use of phytoestrogen plant sources over the past 8 weeks

Intervention groups
Women over 45 years of age are referred to health centers affiliated to Ilam University of Medical Sciences who complain of vasomotor symptoms and want treatment. Intervention group: Portulaca oleracea syrup consumes 3 tablespoons equivalent to 10 cc of syrup daily in 3 meals in the morning, noon, and night. Control group: Placebo syrup consumes 3 tablespoons equivalent to 10 cc of syrup daily in 3 meals in the morning, noon, and night.

Main outcome variables
Intensity and duration of hot flashes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200112046087N7**
Registration date: **2021-09-28, 1400/07/06**
Registration timing: **prospective**

Last update: **2021-09-28, 1400/07/06**
Update count: **0**

Registration date
2021-09-28, 1400/07/06

Registrant information

Name
Hanieh Babaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8877 3521

Email address
haniehbabaei92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of aerial organs portulaca oleracea syrup on menopausal hot flashes

Public title
Evaluation of the effect of portulaca oleracea syrup on hot flashes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Menopausal women over 45 years Stop menstruation for 12 months or more or less than 12 months with follicle-stimulating hormone Having hot flashes at least twice a day Serum FSH more than 40 international units according to laboratory reports Serum LH more than 30 international units according to laboratory reports
Exclusion criteria:
Known physical and mental illnesses such as depression, diabetes, cardiovascular disease, hypertension, hyperlipidemia, liver disease, blood diseases, cancer, gastrointestinal diseases Use of hormone therapy, anticoagulants, sedatives, antidepressants, anticonvulsants, alpha-adrenergic agonists such as clonidine Use plant phytoestrogens such as fennel, soy, black cohosh, flax, primrose oil and vitamin E over the past 8 weeks
Age
From **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment to intervention and control groups Random description: In this study, we will use the block randomization method and in this two-group clinical trial, we will have 4 blocks of volume. For each person who enters the study, a code is obtained from the software and it is determined which group it belongs to (intervention or control). The tool is Random allocation software, which in addition to simple randomization is able to generate random sequences by blocking. To hide, we use Allocation concealment. This method is such that before assigning the individual, the assigned group is not clear by using opaque envelopes sealed with a random sequence, in which each of the random sequences created on It is registered on a card, and the cards are placed in the envelopes of the letter in order. In order to maintain a random sequence, the numbering on the outer surface of the envelopes is done in the same way. Finally, the lids of the envelopes are glued and placed in a box, respectively . Blocking and preparation of envelopes are done by a person not involved in sampling and analyzing the data. In this way, the collector and the analyst, and the participant do not know the type of intervention received and what group each person is in.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this plan, the drug and placebo are prepared by the pharmacist. After preparing the drug, the pharmacist will insert a specific code of the medicine on the bottle. These codes are available to the pharmacist. The shape and size of all drugs are the same and indistinguishable. Therefore, the project implementer uses the drugs randomly for each patient. At the end of the study, after collecting the data, with the help of a pharmacist, the codes related to the drug and the drug facade are distinguished from each other, but information about the drug and placebo is hidden for the analyzer. Only at the end of the study, The codes are decrypted and the necessary information is provided to the executor.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences
Street address
Shahid Chamran Highway - Yemen St. - Shahid Abbas Aarabi St. (Parvaneh) - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences and Health Services -
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2021-06-13, 1400/03/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.113

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
Intensity of hot flashes
Timepoint
2-week monitoring on a daily basis
Method of measurement
Heater et al Scale Questionnaire

2

Description
Duration of hot flashes
Timepoint
2-week monitoring on a daily basis
Method of measurement
Heater et al Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Portulaca oleracea syrup formulated in Shahid Beheshti School of Traditional Medicine consumes 3 tablespoons equivalent to 10 cc daily in 3 meals in the morning, noon, and night for one month. To prepare portulaca oleracea syrup, the aqueous extract of the portulaca oleracea plant, which has been prepared by boiling, is used. In the formulation of portulaca oleracea, 25% sugar and 0.25% carboxymethylcellulose (CMC) are used as thickeners. In addition, microbial preservatives including sodium benzoate and potassium citrate (each with a concentration of 0.1%) are used to make the syrup.
Category
Treatment - Drugs

2

Description
Control group: placebo syrup, which is similar in color, shape and size to portulaca oleracea, is given to the patient 3 tablespoons equivalent to 10 cc of syrup daily for 3 months in 3 meals of the morning, noon and night. Formulation of placebo syrup using carboxymethyl Cellulose (CMC) is prepared as a thickener (0.25%) and sugar (25%) along with caramel food coloring, in a water base. Microbial preservatives including sodium benzoate and potassium citrate (each with a concentration of 0.1%) are used to make placebo syrup.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Ashraf Direkvand Moghadam
Street address
Shahid Beheshti Blvd., Clinic of Ayatollah Taleghani Hospital
City
Ilam
Province
Ilam
Postal code
69391717143
Phone
+98 84 3222 7134
Email
direkvand-a@medilam.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Rasool Choopani Zanjani
Street address
Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences, No. 8, Shams Alley, Valiasr Ave., Tehran, Iran
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Email
sitm@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

Hanieh Babaei

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Traditional Medicine

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Researcher

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Master

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

The questionnaires and the information about the main outcome will be shared with the applicants 3 months after the publication of the results.

When the data will become available and for how long

After publishing results

To whom data/document is available

researchers

Under which criteria data/document could be used

After the publication of the article , for systematic review studies or meta-analysis

From where data/document is obtainable

Dr. Mojgan Tansaz Email: tansaz_mojgan@yahoo.com Phone: 02188773525

What processes are involved for a request to access data/document

Sending a request to the main executor of the project, Dr. Mojgan Tansaz, and reviewing the request by her

Comments