Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of EstroG-100 herbal extract on the improvement of hot flashes in postmenopausal women in two intervention and control groups.

Protocol summary

Study aim
Investigating the effect of EstroG-100 herbal extract on the improvement of hot flashes in postmenopausal women in two intervention and control groups.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 70 patients. The rand function of Excel software was used for randomization.

Settings and conduct
A study was conducted on 70 menopausal women who referred to the gynecology clinic of Ayatollah Taleghani and Imam Hossein (AS) hospitals with hot flashes. The people in the intervention group were given EstroG-100 capsules for 12 weeks, and the people in the control group were given a placebo drug. In order to blind the patients and the researcher, each patient was randomly assigned to the intervention or placebo group based on the rand function of the Excel software.

Participants/Inclusion and exclusion criteria
Study exclusion criteria include: concurrent use of nutritional supplements to manage menopause syndrome, any suspicion of breast and endometrial malignancies, history of using estrogen or progesterone products in the past three months, psychoactive drugs, BMI greater than 40, bleeding Irregular within 1 year after menopause, hysterectomy, uncontrolled blood pressure and ...

Intervention groups
People in the intervention group were given EstroG-100 capsules for 12 weeks and these people consumed 2 capsules every day. People in the control group were also given a placebo drug, which they also took 2 times a day for 12 weeks.

Main outcome variables
Age; marital status; menopause age; underlying disease; pregnancy history; Body Mass index; drug use; drug use; EstroG-100 drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220716055479N1**
Registration date: **2022-10-17, 1401/07/25**
Registration timing: **retrospective**

Last update: **2022-10-17, 1401/07/25**
Update count: **0**

Registration date
2022-10-17, 1401/07/25

Registrant information

Name
Golnaz Fallah Talouki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 4204 1146

Email address
golnaz.fallah.talouki@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-27, 1400/10/06

Expected recruitment end date
2022-03-26, 1401/01/06

Actual recruitment start date
2021-12-27, 1400/10/06

Actual recruitment end date
2022-03-26, 1401/01/06

Trial completion date
2022-04-04, 1401/01/15

Scientific title
Investigating the effect of EstroG-100 herbal extract on the improvement of hot flashes in postmenopausal women in two intervention and control groups.

Public title
Investigating the effect of EstroG-100 herbal extract on the improvement of hot flashes in postmenopausal women in two intervention and control groups.

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Normal BMI Absence of underlying disease
Exclusion criteria:
Unwillingness to participate in the study Use of hormonal drugs containing estrogen and progesterone in the last three months drug use BMI greater than 40 irregular bleeding within 1 year after menopause hysterectomy uncontrolled blood pressure thyroid diseases diabetes mellitus history of hormone related cancers

Age
No age limit

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Actual sample size reached: **70**
More than 1 sample in each individual
Actual sample size in each individual: **35**
One group received the main drug (35 patients, two pills a day for 3 months) and the control group (35 patients, two pills a day for 3 months) received a placebo.

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description of each method: simple randomization, block

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and researchers

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 Beheshti University
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2021-12-21, 1400/09/30
Ethics committee reference number
IR.SBMU.MSP.REC.1400.644

Health conditions studied

1

Description of health condition studied
hot flash
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Investigating the hot flush symptoms based on the patients' answers (the criteria of a questionnaire designed with three states of mild, moderate and severe)

Timepoint
12weeks

Method of measurement
In the first visit, for those eligible to enter the study, they were asked to fill out the form related to severity (mild: sudden hot flush, moderate: sudden hot flush with severe sweating, severe: sudden hot flush with Sweating and interference with daily activities), the number of hot flashes (within a week), should be completed weekly from one week before the treatment to 12 weeks after the treatment and delivered at each visit.In case of not being able to visit these people in person, information will be collected on a weekly basis and during phone calls. Medicines were delivered to people in the clinic during three stages at the beginning of the treatment, the end of the 4th week and the end of the 8th week.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: recipient of ESTROG-100, which this plant extract contains a combination of three plant roots (Cynanchum wilfordii Hemsley plants (Catus family), Phlomis umbrosa Turczaninow (Vanaceae family) and Angelica gigas Nakai (Hycanthus hyacinth)) which is in capsule form by It is prepared by Behestan Daro Company in Iran and is provided to the patient. The patient should take 2 capsules daily for 90 days. In addition, the placebo also contains starch in the same packaging and the same color as the original drug. All the people participating in the study were divided into two main and placebo groups after being informed about the method of conducting the study and after completing the informed consent form. Trainings were provided to the participants regarding how to take the medicine, how to complete the questionnaire based on the severity of the hot flashes (mild, moderate and severe types) and weekly visits to receive the medicine.

Category
Treatment - Drugs

2

Description
Control group: Placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Golnaz Fallah

Street address
Imam Hossein (AS) Medical, below Shahid Madani Metro, Shahid Madani Street

City
Tehran

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Email
info@ehmc.ir

Web page address
https://www.ehmc.ir/

2

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital

Full name of responsible person
Golnaz Fallah

Street address
Velenjak St. , Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1985711151

Phone
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Email
Intl_office@sbmu.ac.ir

Web page address
https://taleghani.sbmu.ac.ir/index.jsp?siteid=88

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Behestan Darou

Full name of responsible person
Dr. Banafsheh Saeedi

Street address
Behestan bldg., #10 Pardis st., Mollasadra Ave

City
Tehran

Province
Tehran

Postal code
141554318

Phone
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Fax

Email
info@behestandarou.com

Web page address
https://www.behestandarou.com/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Behestan Darou

Proportion provided by this source
20

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golnaz Fallah

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Imam Hossein (AS) Medical, below Shahid Madani Metro, Shahid Madani Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Resident

Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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City
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Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data to (non-identifiable individuals)

When the data will become available and for how long
Data access 6-8 months after the publication of the article

To whom data/document is available
researchers

Under which criteria data/document could be used
If the findings obtained in the plan lead to the improvement of women's health and the improvement of menopausal problems

From where data/document is obtainable
The main author

What processes are involved for a request to access data/document
If needed, the study data will be provided to the Shahid Beheshti University of Medical Sciences Research Office and the applicant will be able to access the information through the research office.

Comments