

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

+98 21 2243 9982

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

+98 21 8877 4200

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

Street address

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

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Email

golnaz.fallah.talouki@gmail.com

Person responsible for scientific 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

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Person responsible for updating data

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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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