

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of medroxyprogesteron 10 mg and megestrol 40 mg on vasomotor symptom in menopause women

Protocol summary

Study aim

Comparison of the effects of medroxyprogesteron 10 mg and megestrol 40 mg on vasomotor symptom in menopause women

Design

This study was designed as a triple-blinded randomized clinical trial with parallel groups and a sample size of 40 people in each group

Settings and conduct

The study will be conducted at Kamali Hospital on Menopausal women Patients who signed informed consent will be randomly divided into two groups. The first group will receive Magestrol tablets 40 mg daily for 1 month and the second group will receive medroxyprogesterone 10 mg daily for one month The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Regular exercise program Vegetarian diet Consume soy and its products more than once a week Current use of drugs that affect hot flashes. Symptoms of drug allergy Failure to record the number of hot flashes in the relevant checklists Inclusion criteria: Iranian women 40-60 years old; Married; With a history of childbirth; serum FSH level is more than 40 million units per ml; Lack of known physical or mental illness; Experience at least 3 hot flashes during the day;

Intervention groups

Intervention group1: Magestrol tablets 40 mg daily for 1 month Intervention group 2: Medroxyprogesterone 10 mg daily for one month

Main outcome variables

Intensity of hot flushing and sweating

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210412050945N1**

Registration date: **2021-05-02, 1400/02/12**

Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**

Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Samira Abdollahi

Name of organization / entity

Alborz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3222 2021

Email address

s.abdolahi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of medroxyprogesteron 10 mg and megestrol 40 mg on vasomotor symptom in menopause women

Public title

Comparison of the effects of medroxyprogesteron and megestrol on vasomotor symptom in menopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian women 40-60 years old Married With a history of childbirth; She had the last period 12 month later and serum FSH level is more than 40 million units per ml; Lack of known physical or mental illness; Experience at least 3 hot flashes during the day No addiction or smoking, hookah or alcohol Body mass index less than or equal to 29 Minimum literacy Women with and had at least one of the symptoms of menopausal vasomotor Natural menopause and menopause due to ovarian removal No known mental illness

Exclusion criteria:

Regular exercise program Vegetarian diet Consume soy and its products more than once a week Current use of drugs that affect hot flashes. Symptoms of drug allergy Failure to record the number of hot flashes in the relevant checklists Taking any medicine during research The presence of severe stress during treatment

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Women who consented to participate are randomly selected to receive either medroxyprogesteron or megestrol . Group assignment is determined from a computer-generated table of random numbers. Some opaque envelopes were used for concealment

Blinding (investigator's opinion)

Triple blinded

Blinding description

Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. Patients are unaware of the type of treatment

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2021-01-19, 1399/10/30

Ethics committee reference number

IR.ABZUMS.REC.1399.258

Health conditions studied

1

Description of health condition studied

Menopausal hot flashes

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Intensity of hot flashes

Timepoint

Before and one month after the intervention

Method of measurement

cooperman questionnaire

2

Description

Sweating rate

Timepoint

Before and one month after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Magestrol tablets 40 mg daily for 1 month

Category

Treatment - Drugs

2

Description

Intervention group: Medroxyprogesterone 10 mg daily for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Samira Abdollahi

Street address

Kamali hospital; Kamali alley; Shohada square;
Shahid Beheshti street

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kamali@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

Street address

Vice Chancellor for Research; No.20; Saffarian alley;
45 Metri Golshahr street

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3198764653

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Samira Abdollahi

Position

Assistant professor of gynecology and obstetrics

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Samira Abdollahi

Position

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Samira Abdollahi

Position

Assistant professor of gynecology and obstetrics

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Karaj

City

Alborz

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