

# 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

##### City

Karaj

##### Province

Alborz

##### Postal code

3149779453

##### Phone

+98 26 3222 3021

##### Email

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

##### City

Karaj

##### Province

Alborz

##### Postal code

3198764653

##### Phone

+98 26 3464 3705

##### Email

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

##### Street address

Kamali hospital; Shahid behesh ave.;shohada square;Karaj

##### City

Alborz

##### Province

Alborz

##### Postal code

3149779453

##### Phone

+98 26 3222 2021

##### Fax

##### Email

S.abdolahi@abzums.ac.ir

## Person responsible for scientific 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

**Street address**

Kamali hospital; Shahid behesh ave.;shohada square;Karaj

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**Fax****Email**

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**Person responsible for updating data****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

**Street address**

Kamali hospital; Shahid behesh ave.;shohada square;  
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