

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of the effect of low dose Megestrol (40 mg) and Medroxyprogesterone 10 mg on the quality of life in menopausal women.

#### Protocol summary

##### Study aim

Providing evidence of the effectiveness of megestrol and medroxyprogesterone on the quality of life of menopausal women

##### Design

A randomized, two-group clinical trial, triple-blind, phase 3, will be conducted on 80 patients. The web-based software

<https://www.sealedenvelope.com/simple-randomiser/v1/lists> will be used for randomization.

##### Settings and conduct

A total of 80 menopausal women who meet the inclusion criteria will be recruited as research participants from Kamali Hospital in Karaj. The participants will enter the study using convenience and consecutive sampling methods. They will be randomly assigned using block randomization into one of two groups: the treatment group receiving the desired treatment (oral 40mg Megestrol) and the control group receiving the standard medication (oral 10mg Medroxyprogesterone). To ensure concealment, non-homogeneous block sizes will be used. The study will be conducted in a triple-blind manner, where the data analyst will not be aware of the allocation group. The data related to the received treatment will be entered into the SPSS software as Groups 1 and 2. The outcome assessor will also be blinded to the allocation group. To maintain blinding among participants, identical containers will be provided for medication delivery.

##### Participants/Inclusion and exclusion criteria

Iranian women aged 45 to 55 year. FSH serum level greater than or equal to 40-20 mm units per milliliter (pre menopausal) Do not have a physical or mental illness . Do not have addiction or use of hookah cigarettes or alcohol. The person's body mass index should be less than or equal to 29.

##### Intervention groups

Intervention group 1: recipients of Megestrol 40 one daily  
Intervention group 2: recipients of Medroxyprogesterone 10 every 12 hours

#### Main outcome variables

The results include improvement in vasomotor, physical, psychosocial and sexual areas.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230930059567N1**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

##### Registration date

2023-11-11, 1402/08/20

##### Registrant information

##### Name

Seyede Bahareh Hosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3256 5782

##### Email address

hbahareh53@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-07-22, 1403/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of low dose Megestrol (40 mg) and Medroxyprogesterone 10 mg on the quality of life in menopausal women.

**Public title**  
Comparison of the effect of low dose Megestrol (40 mg) and Medroxyprogesterone 10 mg on the quality of life in menopausal women.

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Iranian women aged 45 to 55 year. FSH serum level greater than or equal to 40-20 mm units per milliliter (pre menopausal) Do not have a physical or mental illness . Do not have addiction or use of hookah cigarettes or alcohol. The person's body mass index should be less than or equal to 29.  
**Exclusion criteria:**

**Age**  
From **45 years** old to **55 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
1. Randomization method: Blocked 2. Randomization unit: Individual 3. Randomization Tool : A randomization list is generated using a web-based software (<https://www.sealedenvelope.com/simple-randomiser/v1/ists>), which is only accessible to a researcher who is not involved in assigning or evaluating the outcomes. At the time of identifying each sample, the allocation group of the patient is announced according to the list through this researcher. 4. Method of generating the random sequence: A randomization list is prepared using a web-based software (<https://www.sealedenvelope.com/simple-randomiser/v1/ists>). The block sizes of 2, 4, and 6 are considered. 5. Explanation of allocation concealment: By considering non-homogeneous block sizes, the allocation sequence will be concealed. In addition, a randomization list is generated, which is only available to a researcher who is not involved in assigning or evaluating the outcomes.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
The study is conducted in a triple-blind manner. In this

type of blinding, the data analyst will not be aware of the treatment group allocation. The data related to the received treatment will be entered into the SPSS software as groups 1 and 2. The outcome assessor will also be unaware of the treatment group allocation. To blind the participants, medications will be given to patients in similar containers.

**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

Alborz University of Medical Sciences , Administrative Town , North Taleghani Blvd , Taleghani Square, Karaj.

##### City

Karaj

##### Province

Alborz

##### Postal code

3149779453

#### Approval date

2023-07-29, 1402/05/07

#### Ethics committee reference number

IR.ABZUMS.REC.1402.114

## Health conditions studied

### 1

#### Description of health condition studied

Menopause symptoms

#### ICD-10 code

N95

#### ICD-10 code description

Menopausal and other perimenopausal disorders

## Primary outcomes

### 1

#### Description

Quality of life score in menqol questionnaire

#### Timepoint

Measuring the quality of life during the study and 1 month after Megestrol consumption

#### Method of measurement

Menopausal Women's Quality of Life Questionnaire -

## 2

### Description

Quality of life score in menqol questionnaire

### Timepoint

Measuring the quality of life during the study and 1 month after Medroxyprogesterone consumption.

### Method of measurement

Menopausal Women's Quality of Life Questionnaire - Persian version (Menqol)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Megestrol Acetate, C24H32O4, 40 milligrams, one tablet per day, for one month, accompanied by a glass of water.

#### Category

Other

### 2

#### Description

Intervention group : Medroxyprogesterone Acetate, C22H32O3, 10 milligrams, one tablet every 12 hours for one month, accompanied by a glass of water.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamali hospital

##### Full name of responsible person

Seyede Bahareh Hosseini

##### Street address

Alborz University of Medical Sciences , Administrative Town, North Taleghani Blvd , Taleghani Square, Karaj

##### City

Karaj

##### Province

Alborz

##### Postal code

3149779453

##### Phone

+98 26 3419 7000

##### Email

info@abzums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Alborz University Of Medical Sciences

##### Street address

Alborz University of Medical Sciences , Administrative Town, North Taleghani Blvd , Taleghani Square, Karaj.

##### City

Karaj

##### Province

Alborz

##### Postal code

3149779453

##### Phone

+98 26 3419 7000

##### Email

Info@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

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Alborz University of Medical Sciences, Administrative Town, North Taleghani Blvd , Taleghani Square, Karaj.

##### City

Karaj

##### Province

Alborz

##### Postal code

3149779453

**Phone**

+98 26 3419 7000

**Email**

samiraabdollahi66@yahoo.com

**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

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Alborz University of Medical Sciences, Administrative Town, North Taleghani Blvd, Taleghani Square, Karaj.

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Phone**

+98 26 3419 7000

**Email**

samiraabdollahi66@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Seyede Bahareh Hosseini

**Position**

Medical intern

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Alborz University of Medical Sciences, Administrative Town, North Taleghani Blvd, Taleghani Square, Karaj.

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Phone**

+98 26 3419 7000

**Fax**

**Email**

hbahareh53@gmail.com

**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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable