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

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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/lists), 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/lists). 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 -

Persian version (Menqol)

2

Description
Quality of life score in menqol questionnaire
Timepoint
Measuring the quality of life during the study and 1 month after Medroxyprogestrone 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
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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.
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3149779453
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Email
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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
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Samira Abdollahi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Seyede Bahareh Hosseini

Position
Medical intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Fax

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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