Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparative Effect of Using Megestrol Alone and its Combination with Metformin in the Treatment of Endometrial Hyperplasia without Atypia

Protocol summary

Study aim

Determining the comparative effect of megestrol alone and its combination with metformin in the treatment of endometrial hyperplasia without atypia

Design

A clinical trial with two parallel intervention groups, single-blind, randomized by lottery method, phase 3 on 60 patients.

Settings and conduct

This studty conducted on women with endometrial biopsy based on endometrial hyperplasia without atypia, referring to Imam Reza and Imam Ali (AS) Shahrekord Clinic in 1401. Samples will be divided into two groups of 30 people, intervention and control, by a simple random method. The control group will use 40 mg of megestrol (Iran Hormone Company) daily for 14 days in a month for 3 months and the second group will use 1000 mg of metformin in addition to megestrol for 3 months. At the end of the study, the bleeding period, BMI, and Cr, ALT, Fbs, AST, CBC, will be re-measured and endometrial biopsy will be taken again from all patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years and under 75 years old, absence of contraindications for using metformin, Hb>10 and GFR>30 and BMI<25 Exclusion criteria: receiving metformin in the previous 6 months, liver and kidney disease, alcohol consumption, malabsorption, pregnancy, and description of insulin injection.

Intervention groups

Two intervention and control groups of 30 people, the control group will use 40 mg of megestrol daily for 14 days in a month for 3 months (from the 14th day of the mense period) and the second group, in addition to megestrol, 1000 mg of metformin for 3 months.

Main outcome variables

Endimetrial Hyperplasia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056361N1**
Registration date: **2023-04-08, 1402/01/19**
Registration timing: **retrospective**

Last update: **2023-04-08, 1402/01/19**
Update count: **0**

Registration date

2023-04-08, 1402/01/19

Registrant information

Name

Paridokht Nourian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4262 7628

Email address

paridokht.nourian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-20, 1400/12/29

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effect of Using Megestrol Alone and its Combination with Metformin in the Treatment of Endometrial Hyperplasia without Atypia

Public title
Effect of Metformin and Megestrol in treatment of Endometrial hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Endometrial Hyperplasia without Hyperplasia No contraindication for the use of Metformin Hb>10 GFR>30 25< BMI 18-75 years old
Exclusion criteria:
Use of Metformin in the previous 6 months Liver disease Malabsorption Pregnancy Insulin injection Kidney disease Alcohol consumption
Age
From **18 years** old to **75 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The researcher assigns a number to the patients using the random allocation rule method and then puts the cards on which the patient's number is written in an envelope in a shuffle. In this method, according to the sample volume, two colors of cards (red and blue or A and B stickers) are poured into the envelope with the same number equal to the total volume of the sample. Then the eligible people entered into the study will randomly take out one of the cards from the envelope and according to the definition of the researcher, if they take the red or A card, they will enter the intervention group, and if they take the blue or B card, they will enter the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The method of blinding is that the patients of the intervention and control groups are unaware of the type of drug being used, and metformin and placebo drugs will be prepared in the form of tablets with the same shape and size. Considering the type of study that is one-sided blind, after randomization And entering the groups, patients in the control group will be given megestrol and placebo, and the patients in the intervention group will be given metformin and megestrol.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord Univercity of Medical Sciences
Street address
Parastar Street,Kashani Ave
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Approval date
2022-03-09, 1400/12/18
Ethics committee reference number
IR.SKUMS.MED.REC.1400.018

Health conditions studied

1

Description of health condition studied
Endometrial hyperplasia
ICD-10 code
N85.01
ICD-10 code description
Benign endometrial hyperplasia

Primary outcomes

1

Description
Percentage of people with Endometrlal Hyperplasia
Timepoint
The Biginning of study and three monthes later
Method of measurement
with Curettage OF endometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 people with endometrial hyperplasia will use 40 mg megestrol and placebo from Ectororco for 14 days per month (14 days after the start of period) for 3 months
Category
Treatment - Drugs

2

Description
Intervention group: 30 people with endometrial hyperplasia who use 1000 mg of metformin for 14 days per month for 3 months in addition to 40 mg of megestrol

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Ali Clinic;Emam Reza Clinic

Full name of responsible person
Paridokht Nourian Najafabadee

Street address
Emam Ali Clinic Shariate Street .Shahrekord

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Elham Reisi

Street address
Kashani street

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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Paridokht Nourian

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Parastar Street, Kashani Avenue,Hajar Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Setare Fatehi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Position
Resident

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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
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy are published

When the data will become available and for how long
The access period will start 6 months after the results are published

To whom data/document is available
Our data is only available to researchers working in scientific and academic institutions

Under which criteria data/document could be used
If there are conditions, all our data will be shared except personal information of people. The use of our data is only allowed for similar research by other researchers. All those who work in scientific and academic centers and decide do similar research can access our data.

From where data/document is obtainable
In order to receive information, all eligible people can collect data by referring to the person responsible for the project. E-mail:paridokht.nourian@gmail.com ,09132326474

What processes are involved for a request to access data/document
To receive information after sending the request, the requests will be reviewed within 10 days, and if the conditions are met, it will be sent to the provided email within 30 days.

Comments