Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of Megestrol and metformin on endometrial hyperplasia in woman attending to Arash hospital

Protocol summary

Study aim
Evaluating the effect of Megestrol and metformin on endometrial hyperplasia

Design
Our sample size is 60 people, with 30 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of blocks considered is 6.

Settings and conduct
This study, clinical trials, double-blind, placebo- control, single center are conducted in Arash women's hospital The random allocation list for patients is solely available to the epidemiologist for 60 patients. When a doctor announces the eligibility of a patient, the methodologist will provide the doctor with the envelope. None of the patients should be aware of the type and treatment process they are seeking. Also, the person evaluating the outcomes is the third person who is unaware of the random allocation process and type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Endometrial hyperplasia No contraindications to treatment with metformin Creatinine clearance greater than 90ml / min Hemoglobin level above 10 Normal hepatic markers Body mass index less than 25. Exclusion criteria:Taking metformin within the past 6 months Impaired hepatic function tests Blood sugar is less than 65 and no more than 200 History of alcohol use disorder History of vitamin B12 pregnancy History of insulin therapy Body mass index less than 25. Allergy to metformin

Intervention groups
group1, beside receiving treatment of 40 mg Megestrol daily for 14 days of menstrual cycle for 3 months , will be treated with placebo (two pills) for12 weeks. Group 2, beside receiving treatment of 40 mg Megestrol daily for 14 days of menstrual cycle for 3 months , will be treated with metformin by dose of 1000 mg (twopills) for12 weeks.

Main outcome variables
Endometrium thickness and uterine bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140820018866N6**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date
2018-09-04, 1397/06/13

Registrant information

Name
Afsaneh Tehranian

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date
2015-11-07, 1394/08/16

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of Megestrol and metformin on endometrial hyperplasia in woman attending to Arash hospital

Public title
Evaluating the effect of Megestrol and metformin on women with endometrial hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Endometrial hyperplasia No contraindications to treatment with metformin Creatinine clearance greater than 90ml / min Hemoglobin level above 10 Normal hepatic markers Body mass index less than 25. 18-72 years old
Exclusion criteria:
Taking metformin within the past 6 months Impaired hepatic function tests Blood sugar is less than 65 and no more than 200 History of alcohol use disorder History of vitamin B12 pregnancy History of insulin therapy Body mass index less than 25. Allergy to metformin
Age
From **18 years** old to **72 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
En Our sample size is 60 people, with30 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of blocks considered is 6.
Blinding (investigator's opinion)
Double blinded
Blinding description
The random allocation list for patients is solely available to the epidemiologist. To hide the random allocation process, 60sequences of treatments will be written accordingly, and then the cards will be placed in sealed envelopes. On each 10-digit random code packet, the order is written and the framework is written that the patient identification number is relevant and the methodologist will simply be aware of the design of the code. When a doctor announces the eligibility of a patient, the methodologist will provide the doctor with the envelope. The treatment is selected based on the type mentioned in the envelope. None of the patients should be aware of the type and treatment process they are seeking. Also, the person evaluating the outcomes is the third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and who is unaware of all the processes performed will be used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Tehran University of Medical Science, Qods Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2015-11-04, 1394/08/13
Ethics committee reference number
IR.TUMS.REC.1394.1101

Health conditions studied

1

Description of health condition studied
Endometrial hyperplasia
ICD-10 code
N85.0
ICD-10 code description
Endometrial hyperplasia

Primary outcomes

1

Description
Improvement of endometrial hyperplasia
Timepoint
befor treatment,3 months after start treatment
Method of measurement

Review of Pathology and evaluation of uterine bleeding

2

Description
The thickness of the uterine endometrium
Timepoint
Every month for 3 times
Method of measurement
Ultrasonography

Secondary outcomes

1

Description
Comparison of BMI
Timepoint
Before and end of the study
Method of measurement
Measure weight and height

2

Description
Comparison of blood and kidney and liver indices
Timepoint
Before and end of the study
Method of measurement
Blood sampling and measuring renal and kidney function test

3

Description
Comparison of FBS
Timepoint
Before and end of the study
Method of measurement
Blood sampling

Intervention groups

1

Description
Control group, beside receiving treatment of 40 mg Megestrol daily for 14 days of menstrual cycle for 3 months , will be treated with placebo (two pills) for12 weeks.
Category
Treatment - Drugs

2

Description
Intervention group, beside receiving treatment of 40 mg Megestrol daily for 14 days of menstrual cycle for 3 months , will be treated with metformin by dose of 1000 mg (twopills) for12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women hospital
Full name of responsible person
Dr. Afsaneh Tehranian
Street address
Arash hospital, Rashid street, Tehranpars, Resalat highway
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Tehran
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1653915981
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
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Tehran University of Medical Science, Qods street, Keshavarz boulevard
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rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Afsaneh Tehranian
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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