

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

Endometrium thickness and uterine bleeding

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

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

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3283

Email address

afsanehtehranian@yahoo.com

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, 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.

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, 60 sequences 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

before treatment, 3 months after start treatment

Method of measurement

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

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Email

afsanehtehranian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Tehran University of Medical Science, Qods street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Email

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

Street address

Arash women hospital, Rashid street, Resalat highway, Tehranpars

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7771 9922

Fax

Email

afsanehtehranian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Tehranian

Position

obstetrician and gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Arash Womens Hospital, Rashid Avenue, Resalat Highway, Tehranparse

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7771 9922

Fax

Email

afsanehtehranian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Afsaneh Tehranian

Position

obstetrician and gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7771 9922

Fax

Email

afsanehtehranian@yahoo.com

Web page address

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