

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison Of The Effect Of adding Metformin to progesterone in The Treatment Of Endometrial Hyperplasia

Protocol summary

Study aim

Determining the Effect of Adding Metformin to Progesterone in the Treatment of Endometrial Hyperplasia In patients referred to Forqani Hospital with the diagnosis of endometrial hyperplasia

Design

Randomized, with a control group with parallel group trial without blinded. Phase 3 on 134 patients(two groups of 67) . Allocation of treatment to groups is done by randomization method with permutation blocks with 6 blocks.

Settings and conduct

Women diagnosed with endometrial hyperplasia referring to Forqani Hospital will be included in the study if they meet the conditions for entering the study after obtaining written consent. By using the block randomization method, treatment allocation will be done randomly in two groups of 67 people. Patients in the first group will be prescribed 500 mg metformin and 20 mg megestrol daily for 3 months. Patients in the second group will only receive 20mg of megestrol for 3 months. Then, after 3 months, for 3 weeks, the patients do not receive medicine, and after 3 weeks, the patients undergo curettage. They will be examined by a pathologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a diagnosis of pathology (AEH) or having a diagnosis of EEC Non-entry criteria: Blood sugar less than 60 or more than 200 mg/dL Alcohol addiction Severe infection Severe chronic disease (impairment of heart, liver, lung or kidney function) Age 18 to 45 years Having informed consent to enter the study

Intervention groups

Intervention group: 500 mg metformin and 20 mg megestrol daily for 3 months. Control group: 20 mg megestrol and placebo for 3 months.

Main outcome variables

endometrial hyperplasia

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20221015056181N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

Roya Hoseinzadeh senseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 9516

Email address

r.hoseinzadeh.s@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Of The Effect Of adding Metformin to progesterone in The Treatment Of Endometrial Hyperplasia

Public title

Treatment Of Endometrial Hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a pathological diagnosis of EEC or AEH Desire to preserve fertility Not having suspicious signs of tissue invasion No hormonal treatment in the last 6 months Obtain informed consent Age 18 to 45 years

Exclusion criteria:

Contraindications for metformin Contraindications for progesterone (megestrol) Use of metformin in the last six months Blood sugar less than 60 or more than 200 mg/dL Using oral contraceptives or estrogen or progesterone Alcohol addiction Severe infection Severe chronic disease (impairment of heart, liver, lung or kidney function)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (<https://www.sealedenvelope.com>)

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

Street address

khaerin salamat hospital, shahid javad delazar Ave

City

Qom

Province

Ghoum

Postal code

3715873355

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.MUQ.REC.1400.191

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**

Endometrial Hyperplasia

Timepoint

Examination of endometrial hyperplasia after 3 weeks of treatment

Method of measurement

Endometrial biopsy

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Metformin and megestrol receptor

Category

Treatment - Drugs

2**Description**

Control group: Megestrol and placebo recipients

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center

Khairin Salamat Hospital
Full name of responsible person
Monire Mirzaei
Street address
Khairin Salamat Hospital , Shahid javad delazar Ave
City
Qom
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3133 3333
Fax
Email
moniremirzaee· ·@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Rahim Aali
Street address
Safashahr s
City
Qom
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3783 5522
Email
aali1400@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person

monire mirzaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Khairin Salamat Hospital, Shahid javad delazar Ave

City

Qom

Province

Ghoum

Postal code

3715873355

Phone

+98 25 3133 3333

Email

moniremirzaee· ·@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

monire mirzaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Khairin Salamat Hospital, Shahid javad delazar Ave

City

Qom

Province

Ghoum

Postal code

3715873355

Phone

+98 25 3133 3333

Fax

Email

moniremirzaee· ·@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

monire mirzaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Khairin Salamat Hospital, Shahid javad delazar Ave

City

Qom

Province

Ghoum

Postal code

3715873355

Phone

+98 25 3133 3333

Fax**Email**

moniremirzaee · ·@gmail.com

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

Total potential data after de-identifying shareable individuals It is an investment.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Available for researchers working in academic and scientific institutions will be.

Under which criteria data/document could be used

According to COPE rules

From where data/document is obtainable

moniremirzaee · ·@gmail.com

What processes are involved for a request to access data/document

via the corresponding author's email

Comments

does not have