Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of adding metformin to progesterone in patients with endometrial hyperplasia admitted to Arash hospital, Tehran, Iran

Protocol summary

Summary

A common treatment for endometrial hyperplasia is Hystrectomy or progesterone. On the other hand, hyper insulinemia can have a direct mytotic effect on the endometrium that inhibit progesterone therapiotic effect the on the endometrium. Metformin and insulin secretion in addition to being able to limit its increase, the ability to reduce the rate of ovarian and adrenal androgen secretion that is secreted.The study of clinical trials between Endometrial hyperplasia patients referred to the hospital a in between 1394-1393 that were detected under sampling to 32 person of any group studied for patients to be fitted into two groups divided. A group treated with progesterone therapy protocol 20-80 mg daily based on the type of hyperplasia in 14 days from the day of the menstrual cycle, 14 for three periods and other groups in addition to the first group receiving treatment progestron treated with metformin for the first 12 weeks of daily 4 weeks in the two numbers (1000 mg) and in the remaining eight weeks of daily (2000 mg) will get. At the end of the course of treatment done another sampling to treatment evaluation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082018866N1**
Registration date: **2014-12-29, 1393/10/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-29, 1393/10/08

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

Tehran University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding metformin to progesterone in patients with endometrial hyperplasia admitted to Arash hospital, Tehran, Iran

Public title

Effects of metformin in the treatment of endometrial hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

In this randomized clinical trial of patients with endometrial hyperplasia admitted to Arash hospital, Tehran, Iran in 2014 were diagnosed by biopsy sample were recruited. Inclusion criteria: women aged 18 to 75 years old with endometrial biopsy confirmed by

endometrial hyperplasia; no contraindications to treatment with metformin; creatinine clearance greater than 90ml / min; using the formula of Cockroft-Gault; normal hepatic markers hemoglobin level above 10; satisfactory condition; physically fit to participate in the study. 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.

Age
From **18 years** old to **75 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Keshavarz blvd., Ghods st.

City
Tehran

Postal code

Approval date
2014-11-24, 1393/09/03

Ethics committee reference number
9111290046

Health conditions studied

1

Description of health condition studied
endometrial hyperplasia

ICD-10 code
N85.0

ICD-10 code description
Hyperplasia of endometrium: NOS cystic glandular-cystic polypoid

Primary outcomes

1

Description
Improvement of endometrial hyperplasia

Timepoint
befor treatment,3 months after start treatment

Method of measurement
Review of Pathology

Secondary outcomes

1

Description
Evaluation of the hepatic effects of metformin in the treatment of patients with Endometrial hyperplasia

Timepoint
start of treatment and 3 months after that

Method of measurement
blood sampling and liver tests measurements

2

Description
Reviews of metformin renal complications in the treatment of patients with Endometrial hyperplasia

Timepoint
start teatment and 3 months after that

Method of measurement
blood sampling and measuring hepatic function test

3

Description
effect of metformin in reduce blood glocose

Timepoint
start treatment and 3 months after that

Method of measurement
blood sampling and Blood glucose measurement

4

Description
Effect of metformin on body mass index

Timepoint
start treatment and 3 months after that

Method of measurement
Measurement of height and weight and body mass index calculator

Intervention groups

1

Description

Control group will be teated with progesterone therapy protocol of 20-80 mg daily based on the type of hyperplasia, 14 days from the day of 14th of the menstrual cycle for three periods.

Category

Treatment - Drugs

2

Description

Intervention group, beside receiving treatment of progestrone in control group , will be treated with metformin by dose of 1000 mg for the first 4 weeks,then follow by 2000 mg metformin in remaining eight weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Dr. Nasim Zarifi

Street address

Arash hospital, Tehranpars, Resalat highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoudi Yonesian

Street address

Tehran University of Medical Sciences, Keshavarz blvd., Ghods st.

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasim Zarifi

Position

MD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Specialist of Obstetrics and gynaecology

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty