

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluating the change of antimullerian hormone three month after metformine therapy in polycystic ovarian syndrome in comparison with control group(women that use placebo instead of metformine)

Protocol summary

Summary

The aim of the study is to introduce antimullerian hormone(AMH) as a factor for measuring response to metformine therapy in polycystic ovarian syndrome. This study is triple blind placebo controlled trial. The sample will be chosen from the women suffer from polycystic ovarian syndrome that refer to the clinic. patients select their kind of treatment with selecting two different way of treatment including metformine and placebo (simple randomized method). Inclusion criteria: 1-Age between 18-45 2- Patient must not suffer from cardiovascular. renal and hepatic disease 3- Patients must be new cases Exclusion criteria: 1- use of oral anticoagulant drug during study 2-stop using metformine during study 3- pregnancy 4-body mass index below eighteen 5- sever hirsutism 6-amenorrhea 7-use of clomiphene citrate or other ovulation induction drugs. The volume of sample is 42 (21 in intervention group 21 in control group). Metformine therapy will be done three times a day for three months in intervention group and in control group with placebo. AMH level and clinical situation of patient will be assessed at the beginning and after three months to identify clinical response to metformine and compare it with AMH level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081918858N1**
Registration date: **2015-02-21, 1393/12/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-21, 1393/12/02

Registrant information

Name

Masoud Rahmanian

Name of organization / entity

Diabet Research Center, Yazd Shahid Sadoghi
University Of Mdical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University Of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the change of antimullerian hormone three month after metformine therapy in polycystic ovarian syndrome in comparison with control group(women that use placebo instead of metformine)

Public title

Evaluating the effect of metformine on antimullerian hormone(AMH) in polycystic ovarian syndrome -a clinical trial

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:1-age between 18-45 2- patientst without cardiovascular. renal and hepatic disease 3- patients must be new cases exclusion criteria: 1- use of oral anticoagulant drug during study 2-stop using metformine during study 3-pregnancy 4-body mass index below eighteen 5- sever hirsutism 6-amenorrhea7-use of clomiphene citrate or other ovulation induction drugs 8- cushing syndrome 9- using drugs that cause hirsutism 10- congenital adrenal hyperplasia 11- hypothyroidism 12- androgen producing ovarian tumors 13- prolactinoma 14- diabet

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Diabetic Research Center, Yazd Shahid Sadoughi
Univercity Of Medical Science

Street address

Yazd Diabet Research Center, Talar Honar Alley,
Bahonar to Azadi Square, Shahid Sadoughi Blvd, Yazd

City

Yazd

Postal code

Approval date

2014-08-17, 1393/05/26

Ethics committee reference number

102128

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Testosterone

Timepoint

before treatment and after three months

Method of measurement

Ng/MI

2

Description

Hip to waist ratio

Timepoint

Before treatment and after three months

Method of measurement

Without any unit

3

Description

FSH

Timepoint

before treatment and after three months

Method of measurement

IU/L

4

Description

LH

Timepoint

before treatment and after three months

Method of measurement

IU/L

5

Description

Age

Timepoint

Before treatment

Method of measurement

Year

6

Description

Hirsutism score

Timepoint

Before treatment and after three months

Method of measurement

Freeman galway score

7

Description

prolactin

Timepoint

before treatment and after three months

Method of measurement

Ng/MI

8

Description

AMH

Timepoint

before treatment and after three months

Method of measurement

Mg

9

Description

BMI

Timepoint

before treatment and after treatment

Method of measurement

m²/kg

10

Description

kind of treatment

Timepoint

Before treatment

Method of measurement

mg

11

Description

17(oh)progesterone

Timepoint

before treatment

Method of measurement

Ng

12

Description

Menstrual disorder

Timepoint

Before treatment and after three months

Method of measurement

Cycles less than 26 days and more than 30 days

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Metformin, 500mg oral tablet, Three

times a day for three months

Category

Treatment - Drugs

2

Description

Control group: Placebo, oral tablet, Three times a day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Clinic

Full name of responsible person

Street address

City

yazd

2

Recruitment center

Name of recruitment center

Khatamolanbia Clinic

Full name of responsible person

Street address

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Diabet Research Center, Yazd Shahid Sadoughi University Of Medical Science

Full name of responsible person

Masoud Rahmadian

Street address

Yazd Diabet Research Center, Talar Honar Alley, Bahonar to Azadi Square, Shahid Sadoughi Blvd, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Diabet Research Center, Yazd Shahid Sadoughi University Of Medical Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Diabet Research Center, Shahid Sadoughi University
of Medical Science

Full name of responsible person

Masoud Rahmanian

Position

Endocrinologist

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