

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effects of metformin on anthropometric, metabolic and hormonal changes in polycystic ovarian syndrome

Protocol summary

Summary

The polycystic ovary syndrome (PCOS) is an extremely common disorder. Although PCOS is known to be associated with reproductive morbidity and increased risk for endometrial cancer, diagnosis is especially important because PCOS is now thought to increase diabetes and cardiovascular risk. Objective: The main objective of the present study was to determine the effects of metformin on anthropometric, metabolic and hormonal changes in PCOS. Design: This is a non randomized before and after clinical trial. Setting and conduct: Infertile reproductive age women referred to Infertility clinic Fatemie, Hospital, Hamedan, Iran between May 2008 and August 2009. Participants: 28 women with PCOS according to the Rotterdam criteria. Intervention: Metformin 500mg orally TDS for 12 weeks. Main outcome: The anthropometric characteristics of the patients and mean ovarian volume and plasma level of FBS, lipid profile, LH, FSH, Estradiol, Testosterone, 17OHP, DHEAS, CRP, Homocysteine before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903244176N1**

Registration date: **2008-07-26, 1387/05/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-07-26, 1387/05/05

Registrant information

Name

Nosrat Neghab

Name of organization / entity

Hamedan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamedan university of medical science/Pro vice chancellor for research

Expected recruitment start date

2008-07-26, 1387/05/05

Expected recruitment end date

2009-10-27, 1388/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of metformin on anthropometric, metabolic and hormonal changes in polycystic ovarian syndrome

Public title

The effects of metformin on anthropometric, metabolic and hormonal changes in polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Reproductive age women referred due to infertility. Polycystic ovarian syndrome was defined as the presence of more than 12 cysts, 2-9 mm in diameter in one plane in at least one ovary and increased stroma, usually combined with increased ovarian volume >10 ml in sonography and clinical or biochemical

hyperandrogenism. Subjects should have normal prolactin, thyroid, renal and hematological indices. No participant had received metformin or other hormonal treatment within the 3 months prior to study. Exclusion criteria included concurrent hormone therapy within the previous 6 weeks, any chronic disease that could interfere with the absorption, distribution, metabolism or excretion of metformin, renal or liver disease, being an smoker, doing intense physical activity, having lost 3 kg of body weight in the 2 months preceding the study

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Hamedan university of medical science/Ethics committee

Street address

School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street, Research committee

City

Hamedan

Postal code**Approval date**

2008-07-23, 1387/05/02

Ethics committee reference number

16/35/9/56566

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Waist to hip circumference

Timepoint

12 weeks

Method of measurement

physical exam

2**Description**

BMI

Timepoint

12 weeks

Method of measurement

kilogramm/M2 physical exam

3**Description**

Menstrual cycles

Timepoint

12 weeks

Method of measurement

History taking

4**Description**

Ovarian volume

Timepoint

12 weeks

Method of measurement

Trans vaginal sonography

5**Description**

Testosterone

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

6**Description**

LDL

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

7

Description

HDL

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

8

Description

TG

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

9

Description

Cholesterol

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

10

Description

Homocysteine

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

11

Description

CRP

Timepoint

12 weeks

Method of measurement

Lab test, Blood sampling

Secondary outcomes

1

Description

Weight

Timepoint

12weeks

Method of measurement

Physical exam

2

Description

Blood pressure

Timepoint

12weeks

Method of measurement

Physical exam

3

Description

Acne

Timepoint

12weeks

Method of measurement

Physical exam

4

Description

Hirsutism

Timepoint

12weeks

Method of measurement

Physical exam

5

Description

LH

Timepoint

12weeks

Method of measurement

Lab test, Blood sampling

6

Description

FSH

Timepoint

12weeks

Method of measurement

Lab test, Blood sampling

7

Description

Estradiol

Timepoint

12weeks

Method of measurement

Lab test, Blood sampling

8

Description

17OH Progesterone

Timepoint

12weeks

Method of measurement

Lab test, Blood sampling

9

Description

DHEAS

Timepoint

12weeks

Method of measurement

Lab test, Blood sampling

Intervention groups

1

Description

All patients received 1500 mg metformin per day (500 mg three times a day) for 12 weeks orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility clinic, Fatemie Hospital, Hamedan, Iran

Full name of responsible person

Dr Marzie Farimani Sanoee

Street address

Infertility clinic, Fatemie Hospital

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan university of medical sciences/Pro vice chancellor for research

Full name of responsible person

Dr Abas Zamanian

Street address

Research committee, School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan university of medical sciences/Pro vice chancellor for research

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Marzie Farimani Sanoee

Position

Associated professor

Other areas of specialty/work

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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