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: empty
Registration timing: na
Last update: empty
Update count: 0
Registration date
empty
Registrant information
Name
Nosrat Neghab
Name of organization / entity
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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 ovary 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 a 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
<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Method of measurement</th>
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<tr>
<td>12 weeks</td>
<td>Lab test, Blood sampling</td>
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### Description

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<tr>
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<tr>
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<td>Method of measurement</td>
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### Secondary outcomes

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<tr>
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### Description

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<th>Weight</th>
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<tr>
<td>Timepoint</td>
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<td>Method of measurement</td>
<td>Physical exam</td>
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### Description

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<td>Method of measurement</td>
<td>Physical exam</td>
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### Description

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<tr>
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<td>Method of measurement</td>
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### Description

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### Description

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<tr>
<td>Timepoint</td>
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<tr>
<td>Method of measurement</td>
<td>Lab test, Blood sampling</td>
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### 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 Fakhmideh Street
City
Hamedan
Grant name
Hamedan university of medical sciences/Pro vice chancellor for research
Grant code / Reference number
empty
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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Web page address
www.umsha.ac.ir
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