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
Hamedan university of medical sciences
Country
Iran (Islamic Republic of)
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+98 81 1827 7012

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nosratneghab@umsha.ac.ir

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 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>Step</th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
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<tr>
<td></td>
<td>Hirsutism</td>
<td>12 weeks</td>
<td>Lab test, Blood sampling</td>
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<td>5</td>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
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<tr>
<td></td>
<td>LH</td>
<td>12 weeks</td>
<td>Lab test, Blood sampling</td>
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<tr>
<td></td>
<td>FSH</td>
<td>12 weeks</td>
<td>Lab test, Blood sampling</td>
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<td>7</td>
<td>Description</td>
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<td>Estradiol</td>
<td>12 weeks</td>
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<td>8</td>
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<tr>
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<td>17OH Progesterone</td>
<td>12 weeks</td>
<td>Lab test, Blood sampling</td>
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<td>9</td>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
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<tr>
<td></td>
<td>DHEAS</td>
<td>12 weeks</td>
<td>Lab test, Blood sampling</td>
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**Secondary outcomes**

<table>
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<th>Step</th>
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<th>Timepoint</th>
<th>Method of measurement</th>
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<tbody>
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<td>1</td>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
</tr>
<tr>
<td></td>
<td>Weight</td>
<td>12 weeks</td>
<td>Physical exam</td>
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<td>2</td>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
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<td></td>
<td>Blood pressure</td>
<td>12 weeks</td>
<td>Physical exam</td>
</tr>
<tr>
<td>3</td>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
</tr>
<tr>
<td></td>
<td>Acne</td>
<td>12 weeks</td>
<td>Physical exam</td>
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</table>

**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

| empty |

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 |
| Street address | School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street |
| City | Hamedan |

Person responsible for scientific inquiries

Contact

| Name of organization / entity | Hamedan University of Medical Sciences |
| Full name of responsible person | Dr Marzie Farimani Sanoee |
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| Other areas of specialty/work |
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| City | Hamedan |

Person responsible for updating data

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 |
| Street address | School of Medicine, Hamedan University of Medical Sciences, Shahid Fahmideh Street |
| City | Hamedan |
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