Comparison of therapeutic effects of metformin and simvastatin in PCOS

Protocol summary

Summary
The purpose of the study is to compare the therapeutic effects of metformin and simvastatin in Polycystic Ovarian Syndrome. A total of 60 women referred to Alzahra hospital of Tabriz who are in reproductive age and have PCOS will be recruited and assigned to receive metformine (1500 mg daily) or simvastatin (20 mg daily) for 3 months. Improvements in menstrual regularity and hyperandrogenic state and clinical and laboratory parameters will be measured before and 3 months after the interventions and compared between groups.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT201012285487N2
Registration date: 2011-02-24, 1389/12/05
Registration timing: retrospective

Registrant information
Name
Shabnam Pourabolghasem
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1442 1471
Email address
pourabolghasemsh@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source
Alzahra hospital

Expected recruitment start date
2011-01-05, 1389/10/15
Expected recruitment end date
empty

Inclusion/Exclusion criteria
Inclusion criteria: age 20 to 40 years, having PCOS means: A - clinical symptoms and / or biochemical parameters of hyperandrogenism + irregular mens, having normal levels of bilirubin, creatinine, BUN, SGOT, SGPT, TSH
Exclusion criteria: Presence of congenital adrenal hyperplasia, hyperprolactinemia, Cushing’s syndrome, androgen secreted by tumors, thyroid disease, diabetes mellitus, hypertension, history of cardiovascular disease, Using OCP and other steroid hormones or any drugs affecting ovarian function, insulin sensitivity or lipid profiles, Pregnancy, incidence of any adverse effects (liver and renal function tests elevation) during treatment

Age
From 20 years old to 40 years old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator’s opinion)
Randomized

Blinding (investigator’s opinion)
Double blinded

Placebo
Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Vice-chancellor for Research, Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht St., Tabriz
City
Tabriz
Postal code
Approval date
2010-09-27, 1389/07/05
Ethics committee reference number
5/4/4889

Health conditions studied

1
Description of health condition studied
PCOS
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1
Description
BP
Timepoint
Before clinical trial and three months after
Method of measurement
MmHg by using a mercury manometer

2
Description
Weight
Timepoint
Before clinical trial and three months after
Method of measurement
By Digital Scale

3
Description

BMI
Timepoint
Before clinical trial and three months after
Method of measurement
Weight to kilograms / the square of height in meters

4
Description
Hirsutism
Timepoint
Before clinical trial and three months after
Method of measurement
Hirsutism score

5
Description
Acne
Timepoint
Before clinical trial and three months after
Method of measurement
Clinical Finding

6
Description
Irregular Mens
Timepoint
Before clinical trial and 3 months after
Method of measurement
Clinical Finding

7
Description
Prolactin
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

8
Description
GTT
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

9
Description
FSH
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

10
Description
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<th>LH</th>
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<td><strong>Timepoint</strong></td>
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<td>Before clinical trial and three months after</td>
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<td><strong>Method of measurement</strong></td>
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<td><strong>Description</strong></td>
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<td>Total testosterone</td>
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<td><strong>Description</strong></td>
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<td>Free testosterone</td>
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<td><strong>Timepoint</strong></td>
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<td><strong>Description</strong></td>
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<td>SHBG</td>
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<td>DHEAS</td>
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<td><strong>Description</strong></td>
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<td>Serum Insulin</td>
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<td><strong>Timepoint</strong></td>
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<td><strong>Description</strong></td>
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<td>Insulin sensitivity Index</td>
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<td>Total cholesterol</td>
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<td>HDL, LDL</td>
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**Secondary outcomes**

empty

**Intervention groups**

**1**

| **Description** |
| Metformin, 1500 mg daily, orally for 3 months |
| **Category** |
| Treatment - Drugs |

**2**

| **Description** |
| Simvastatin, 20 mg daily, orally for 3 months |
| **Category** |
| Treatment - Drugs |

**Recruitment centers**

**1**

| **Recruitment center** |
| Alzahra Hospital |
| **Full name of responsible person** |
| Dr. Fatemeh Kazemivand |
Street address
Baghshomal Square - South Artesh Avenue.
City
Tabriz

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Alzahra Hospital Research Center
Full name of responsible person
Dr. Fatemeh Kazemivand
Street address
Baghshomal Square - South Artesh Avenue.
City
Tabriz
Grant name

Title of funding source
Alzahra Hospital Research Center
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
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Kazemivand
Position
Obstetrics and gynecology resident
Other areas of specialty/work
Street address
Baghshomal Square - South Artesh Avenue
City
Tabriz
Postal code
Phone
+98 41 1553 9161
Fax
Email
fatemehkazemivand@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Kazemivand
Position
Obstetrics and gynecology resident
Other areas of specialty/work
Street address
Alzahra Hospital - South Artesh Avenue
City
Tabriz
Postal code
Phone
+98 41 1553 9161
Fax
Email
pourabolghasemsh@tbzmed.ac.ir
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