Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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**

Last update:
Update count: **0**

Registration date

2011-02-24, 1389/12/05

Registrant information

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Shabnam Pourabolghasem

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Alzahra hospital

Expected recruitment start date

2010-10-07, 1389/07/15

Expected recruitment end date

2011-01-05, 1389/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of metformin and simvastatin in PCOS

Public title

Comparison of therapeutic effects of metformin and simvastatin in PCOS

Purpose

Treatment

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
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

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 three months after
Method of measurement
Clinical Finding

7

Description
Prolactin
Timepoint
Before clinical trial and 3 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
LH
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

11

Description
Total testosterone
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

12

Description
Free testosterone
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

13

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

14

Description
DHEAS
Timepoint
Before clinical trial and 3 months after
Method of measurement
Laboratory results

15

Description
Serum Insulin
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

16

Description
Insulin sensitivity Index
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

17

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

18

Description
Total cholesterol
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

19

Description
HDL, LDL
Timepoint
Before clinical trial and three months after
Method of measurement
Laboratory results

20

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

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
Name of 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
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
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Person responsible for scientific inquiries

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Shabnam Pourabolghasem
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Person responsible for updating data

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Fax
Email
pourabolghasemsh@tbzmed.ac.irsh_pour_gm@yahoo.com
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