

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The effect of atorvastatin on biochemical and hemostatic profile of patients with polycystic ovary syndrome

Protocol summary

Summary

This study will be performed at the Research center for bone health -imam reza hospital tabriz.regarding previous we select 40 pts and using Rand List software divide them into two groups.In the first group Atorvastatin(Razak com.)20 Mg daily and in the second group OCP are given. weight, abd.circumference, BMI. biochemical markers including FPG, serum insulin, hsCRP, LDL, HDL, Tg, Cholesterol, LH, Fibrinogen, testosterone , DHEAS and homocystein before and after 3 months of prescribing the above drugs . Results will be analysed using SPSS 16 software .To compare qualitative variables we will use chi-square and to compare quantitative variables we will use Independant sample t test and repeated measure of Annova. Level if significance is 0.05.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208299626N1**

Registration date: **2012-08-29, 1391/06/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-29, 1391/06/08

Registrant information

Name

Majid Mobaseri

Name of organization / entity

Tabriz university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy for research, Tabtiz University of Medical Sciences

Expected recruitment start date

2012-04-04, 1391/01/16

Expected recruitment end date

2013-04-05, 1392/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of atorvastatin on biochemical and hemostatic profile of patients with polycystic ovary syndrome

Public title

The effect of atorvastatin on biochemical and hemostatic profile of patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteriion: all patients with PCOS. Exclusion criteria: any disease in recent month; ingestion of any drug that might affect insulin level, lipids and ovary function in recent 6 months; previous statin use; any chanfe in lifestyle during study; pregnancy and lactation

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Tabriz University of Medical Sciences Ethics Committee

Street address

Faculty of Medicine- Daneshgah Ave. Tabriz

City

Tabriz

Postal code

Approval date

2012-04-04, 1391/01/16

Ethics committee reference number

9139

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

Biochemical and Hemostatic profile

Timepoint

Three month

Method of measurement

Paraclinical

Secondary outcomes

1

Description

Alternation in biochemical and hemostatic profile

Timepoint

Three month

Method of measurement

Paraclinical

Intervention groups

1

Description

Atrovastatin in case group

Category

Treatment - Drugs

2

Description

OCP in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bone disease health center

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Rashidi

Street address

Medicine faculty- Daneshgah ave- Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

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

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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