Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Oral simvastatin effect on reproductive outcomes and biochemical metabolic parameters in PCOS patients undergoing IVF

Protocol summary

Summary

This is a non-randomized clinical trial, controlled with metformin, wich deisign toEvaluating the changes in outcome and serum metabolic biochemical parameters after oral Simvastatin administration in patients with poly cystic ovary syndrome. All patients in reproductive age with pcos that refer to infertility clinic of Fatemieh hospital of Hamadan, and without history of endocrine disease, Recent use of lipid-lowering drugs and statins are enrolled in study.Eligible patients (n = 25) after signing an informed consent, are divide in metformin and Simvastatin groups. patients on Simvastatin group, will treated with 8 weeks 20 mg daily Simvastatin and 500 mg daily metformin and patients in control group(Metformin) use of 500mg daily metformin for 8 week. The primary outcome of this study is to determine the biochemical parameters at the end of the fourth week and eighth week. At the end of study the mean of biochemical parameters in the two groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110811408N1**
Registration date: **2013-01-30, 1391/11/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-01-30, 1391/11/11

Registrant information

Name

Somayeh Enayati

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8966

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s.enayati@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

The cost of this project provided by the Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral simvastatin effect on reproductive outcomes and biochemical metabolic parameters in PCOS patients undergoing IVF

Public title

Evaluating the changes in outcome and serum metabolic biochemical parameters after oral Simvastatin administration in patients with poly cystic ovary syndrome undergoing IVF

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: All patients in reproductive age with pcos that refer to infertility clinic of fatemieh hospital of Hamadan, that agreed to participate in the study and complete the informed consent, and without history of

endocrine disease, Recent use of lipid-lowering drugs and statins. exclusion criteria: don't referring After getting treatment, arbitrary discontinuation of treatment

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: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Hamadan University of Medical Sciences

Street address
Hamadan- mahdiyeh Street - Hamadan University of Medical Sciences - Department of Research and Technology - Office of the Ethics Committee of the University

City
hamadan

Postal code

Approval date
2012-08-16, 1391/05/26

Ethics committee reference number
16/35/9/1828/د/پ

Health conditions studied

1

Description of health condition studied
Poly Cystic Ovarian Syndrom

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome

Primary outcomes

1

Description
HDL

Timepoint
before of study and the fourth and eighth weeks

Method of measurement
with Biochemical laboratory techniques and in mg per deciliter

2

Description
LDL

Timepoint
before of study and the fourth and eighth weeks

Method of measurement
with Biochemical laboratory techniques and in mg per deciliter

3

Description
TG

Timepoint
before of study and the fourth and eighth weeks

Method of measurement
with Biochemical laboratory techniques and in mg per deciliter

4

Description
Testestroon

Timepoint
before of study and the fourth and eighth weeks

Method of measurement
with Biochemical laboratory techniques and in mg per deciliter

5

Description
GTT

Timepoint
before of study and the fourth and eighth weeks.

Method of measurement
with Biochemical laboratory techniques and in mg per deciliter

Secondary outcomes

empty

Intervention groups

1

Description
Tab Simvastatin group 20 mg daily and Tab Metformin 500 mg daily for 8 week

Category
Treatment - Drugs

2

Description
Tab Metformin 500 mg daily for 8 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
woman clinics of Hamadan Fatemieh hospital
Full name of responsible person
dr Somayeh Enayati
Street address
hamadan-kermanshah street-fatemiyeh hospital
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences and Health ser
Full name of responsible person
Dr Heidar Tavilani
Street address
Hamadan University of Medical Sciences, Shahid-fahmideh Street, Hamadan
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences and Health ser
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
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Hamadan University of Medical Sciences and Health services
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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