

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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, with design to evaluate the changes in outcome and serum metabolic biochemical parameters after oral Simvastatin administration in patients with polycystic ovary syndrome. All patients in reproductive age with PCOS that refer to infertility clinic of Fatemeh 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 divided into metformin and Simvastatin groups. Patients on Simvastatin group, will be 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 weeks. 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

##### Email address

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 polycystic ovary syndrome undergoing IVF

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: All patients in reproductive age with PCOS that refer to infertility clinic of Fatemeh 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/پ/د

## 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

Testestroom

#### 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****Name of organization / entity**

Hamadan University of Medical Sciences and Health services

**Full name of responsible person**

Dr Somayeh Enayati

**Position**

Resident of Obstetrics and Gynecology

**Other areas of specialty/work****Street address**

Fatemiyeh Hospital, Kermanshah Street, Hamadan

**City**

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+218 8968966

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**Email**somayeh2.enayati@gmail.com  
sompad.hamedan@gmail.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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sompad.hamedan@gmail.com**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Resident of Obstetrics and Gynecology, Faculty of Medicine, Hamadan University of Medical Sciences

**Full name of responsible person**

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sompad.hamedan@gmail.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*