

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Simvastatin versus Atorvastatin in the treatment of mild to moderate depression in post CABG patients: a double blind randomized clinical trial

#### Protocol summary

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#### Summary

Patients will be randomized into two 25 participants groups according to Random Permuted Block. One group will receive 20 mg Simvastatin per day for 6 weeks and the other group will receive 20 mg Atorvastatin per day for 6 weeks. All participants will be evaluated by HAM-D questionnaire at weeks 0, 2, 4, and 6. Side effects of the drugs will be checked at weeks 1, 2, 4, and 6. At the end of the study the effects and the side effects of the both drugs will be compared. At the beginning of the study, at week 2 and at week 6, liver enzymes (ALT, AST, ALK, and Bilirubin) and lipids (TG, Total Cholesterol, LDL, and HDL) will be checked.

#### Recruitment status

**Recruitment complete**

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2014-10-28, 1393/08/06

#### Expected recruitment end date

2014-12-27, 1393/10/06

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201410271556N68**

Registration date: **2014-10-28, 1393/08/06**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2014-10-28, 1393/08/06

#### Registrant information

#### Name

Shahin Akhondzadeh

#### Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 21 5541 2222

#### Email address

#### Scientific title

Simvastatin versus Atorvastatin in the treatment of mild to moderate depression in post CABG patients: a double blind randomized clinical trial

#### Public title

Comparison between the effect of Simvastatin and Atorvastatin in controlling post cardiac surgery depression.

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients who have undergone coronary bypass surgery. 2. Patients who based on DSM-IV have major depression and based Hamilton rating scale for depression (Ham-D 17 items) their score is => 18. 3. No psychiatric symptoms 4. Not receiving psychotropic drugs 5. Not receiving antidepressants during the last month 6. Do not receiving ECT during the last two months 7. No thyroid problem 8. Age between 15 and 80 years 9. No liver dysfunction 10. No Muscular disorders 11. Not receiving other antilipid drugs 12. No hypersensitivity to statins 13. LDL => 80 14. Liver enzymes not being elevated at the time of recruitment

15. No life threatening disease 16. No neurological disorders 17. Not being pregnant 18. No breast feeding 19. Giving informed consent Exclusion criteria: 1. Existing other disorders rather than depression, including Bipolar disorders, Schizophrenia, and other psychotic disorders 2. History of drug abuse or dependency within the last three months 3. Probability of suicide or its tendency during the last year 4. Women who are going to be pregnant within the next few months 5. Women who use OCP for pregnancy prevention 6. Patients who have received antidepressants during the last month 7. Patients who have received ECT within the last two months 8. Patients who need un-usual psychiatric treatments 9. Patients with liver dysfunction 10. Muscular disorders 11. Receiving other antilipid drugs 12. Hypersensitivity to statins 13. LDL < 80 14. Elevated liver enzymes at the time of recruitment 15. Life threatening diseases 16. Neurological diseases

**Age**

From **15 years** old to **80 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

Tehran University of Medical Sciences Ethics Committee

**Street address**

Tehran University of Medical Sciences, Keshavarz Boulevard, Ghods Street

**City**

Tehran

**Postal code****Approval date**

2012-10-30, 1391/08/09

**Ethics committee reference number**

19165

**Health conditions studied****1****Description of health condition studied**

Depression

**ICD-10 code**

F32.1

**ICD-10 code description**

Moderate depressive episode

**Primary outcomes****1****Description**

Depression

**Timepoint**

At the starting time, two weeks after intervention, four weeks after intervention, and six weeks after intervention

**Method of measurement**

Hamilton Depression Questionnaire

**Secondary outcomes****1****Description**

Drugs side effects

**Timepoint**

First week after starting the study, second week after starting the study, fourth week after starting the study, and sixth week after starting the study

**Method of measurement**

Drug side effects checklist

**Intervention groups****1****Description**

Second group will receive 20 mg Atorvastatin per day for 6 weeks.

**Category**

Treatment - Drugs

**2****Description**

First group will receive 20 mg Simvastatin per day for 6 weeks.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Tehran Heart Center

**Full name of responsible person**

Dr. Seyed Hesameddin Abbasi

**Street address**

Tehran Heart Center, North Kargar Street

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Younesian

**Street address**

Tehran University of Medical Sciences, Ghods Street,  
Keshavarz Boulevard

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran Heart Center

**Full name of responsible person**

Dr. Seyed Hesameddin Abbasi

**Position**

PhD student in Epidemiology

**Other areas of specialty/work**

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1411713138

**Phone**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Faculty of Medicine, Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

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Tehran Heart Center

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Dr. Seyed Hesameddin Abbasi

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PhD student in Epidemiology

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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*