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

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 begining of the study, at week 2 and at week 6, liver enzymes (ALT, AST, ALK, and Bilirubin) and lipids (TG, Total Cholestrol, LDL, and HDL) will be checked.

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
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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

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 withing 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 Strret

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

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Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

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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
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PhD student in Epidemiology

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Person responsible for scientific inquiries

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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