

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the efficacy of atorvastatin in the treatment of major depressive disorder.

Protocol summary

Summary

This is a randomized, double-blind clinical trial to evaluate the efficacy of Atorvastatin in treating major depressive disorder. In this study 60 patients, referred to psychiatry ward of Farshchian Hospital will be enrolled in the study with consent inform ,who have been diagnosed as MDD based on DSM-IV TR and their age is between 18 to 50 years and have no known systemic disease and hypercholesterolemia and also have no history of illegal substance abuse. The patients will be divided into two groups based on randomized blocks. The case group will receive 40 mg citalopram along with atorvastatin 20 mg per day and the control group will receive 40 mg citalopram along with placebo. Prior to start the treatment, they will undergo ALT, AST, LDH, CPK, LDL, HDL, CHOL, and TG tests. Before the treatment and the intervals of 3, 6 and 12 weeks after the treatment, the patients' depression will be assessed through Hamilton Depression Scale and finally the improvement rate of the both groups compared to each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208261743N9**

Registration date: **2012-09-09, 1391/06/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-09, 1391/06/19

Registrant information

Name

Mohammad Haghighi

Name of organization / entity

Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 4184

Email address

haghighi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of atorvastatin in the treatment of major depressive disorder.

Public title

Effect of atorvastatin in in the treatment of major depressive

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: - Diagnosed as MDD according to DSM-IV TR - Age between 18 to 50 years - No other psychiatric disorders along with MDD - No other debilitating physical illness along with MDD - No hypercholesterolemia (Chol > 200) - No history of substance abuse during one past year - No known gastrointestinal disease - No abnormal

hepatic enzymes (AST and ALT) - No abnormal LDH, 10-CPK Exclusion Criteria: - Severe gastrointestinal complication during the study - Increased CPK, LDH during the study - Increased hepatic enzymes during the study (AST, ALT)

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Fahmideh str.Hamadan

City

Hamadan

Postal code

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

1276/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Severity of symptoms of Depression

Timepoint

Baseline and 3weeks, 6weeks ,12weeks after treatment

Method of measurement

Hamilton depression rating scale

Secondary outcomes

empty

Intervention groups

1

Description

administration of citalopram+placebo

Category

Treatment - Drugs

2

Description

administration of citalopram+atorvastatin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Mohammad Haghghi

Street address

Farshchian Hospital

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

Full name of responsible person

Dr.Mohammad Ahmadpanah

Street address

honarestan Str

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research center for behavioral disorders and substance abuse, Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

saeed khodakarami

Position

resident of psychiatry

Other areas of specialty/work

Street address

farshchian hospital

City

Hamadan

Postal code

Phone

+98 81 1828 5015

Fax

Email

saeed_kh57@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Mohammad Haghghi

Position

Assistant Professor of Psychiatry

Other areas of specialty/work

Street address

Farshchian Hospital

City

Hamadan

Postal code

Phone

+98 81 1828 5015

Fax

Email

haghghi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

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