

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of atorvastatine -as an adjuant- in reduction of negative symptoms in schizophrenic inpatients

Protocol summary

Summary

This study is a randomized double-blind clinical trial which is performed on patients with schizophrenia diagnosis admitted in Goolesan hospital psychiatric ward. 40 male and female patients, who are diagnosed as schizophrenics during interviews done by at least two psychiatrists according to DSM-IV TR and have inclusion criteria, will be divided randomly to intervention and control groups (Atorvastatin plus Risperidone and placebo plus Risperidone). Researcher and person who evaluates will be unaware of this choice. In both groups, 2 mg of Risperidone per day will be started and will be increased to 6 mg per day if it is necessary. In intervention group, Atorvastatin at a dose of 20 mg per day and in control group placebo prepared like Atorvastatin will be added to Risperidone. These two groups will receive placebo or drug for 6 weeks, Biperiden up to 6 mg per day will be permitted if motor complications occur or if it is necessary. Patients can receive up to 2 mg Clonazepam per day. All patients will be checked at the start and weeks 1, 3, 4 and 6 with PANSS criteria to evaluate negative symptoms of schizophrenia and two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202067290N1**
Registration date: **2012-03-22, 1391/01/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-22, 1391/01/03

Registrant information

Name

Mehdi Sayyah Bargard

Name of organization / entity

Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Jundishapur university of medical sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of atorvastatine -as an adjuant- in reduction of negative symptoms in schizophrenic inpatients

Public title

Evaluation of atorvastatine effect in reduction of negative symptoms in inpatients with schizophrenia disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a diagnosis of schizophrenia according to DSM-IV-TR; an overall score of 50 or higher on the PANSS scale; 15 or higher negative score in PANSS scale; age range between 70-18 years; duration of at least 1

year from onset of the illness. Exclusion criteria: history of sensitivity to statins; active liver disease or inexcusable stable increase in liver enzymes ; renal failure; serious medical illness; substance abuse or dependency in recent months; pregnancy; lactation; other simultaneous psychiatric disorders requiring medication; desire to homicide or suicide; having dementia and severe cognitive impairments not bound to schizophrenia; organic brain disorders such as seizure; severe mental retardation and Parkinsonism; consumption of oral antipsychotics during last month or long-acting injectable forms within three months; Concomitant use of other drugs such as antidepressants; lithium which may interfere in treatment; drug-resistant schizophrenia disorder; , lack of response to appropriate dosage and duration of Risperidone.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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**

Jundishapur university of medical sciences

Street address

Vice chancellor for research, Jundishapur university of medical sciences

City

Ahwaz

Postal code**Approval date**

2012-02-04, 1390/11/15

Ethics committee reference number

ETH-354

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

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Negative sign

Timepoint

at the end of weeks 1 ,3 ,4 and 6

Method of measurement

PANSS questionnaire

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

Positive sign

Timepoint

at the end of weeks 1 ,3 ,4 and 6

Method of measurement

PANSS questionnaire

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

Intervention group: 6 mg risperidon + Atorvastatin 20 mg, daily

Category

Treatment - Drugs

2**Description**

Control group: 6 mg risperidon + Placebo, daily

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Psychiatry group, Golestan Hospital

Full name of responsible person

Dr. Mehdi Sayyah Bargard

Street address**City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jundishapur University of Medical Sciences

Full name of responsible person

Mostafa Fegghi

Street address

Jundishapur university

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jundishapur 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

Jundishapur University of Medical Sciences

Full name of responsible person

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Position

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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