Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Determine the effect of Simvastatin to control negative symptoms of atypical antipsychotics in patients with schizophrenia

Protocol summary

Summary

In the present study, the effect of adding Simvastatin to Atypical antipsychotics in reducing negative symptoms of schizophrenia patients is desired. This study is a randomized, double-blind, Placebo-controlled, single-center, the two trials is the inclusion criteria include: (1) Schizophrenia, (2) negative score over 15 in PANSS Exclusion criteria: (1) Cancel the patients participating in the study, (2) The adverse drug reactions of patients is 30. Patients during the 6-week study by the PANSS Scale (Positive & Negative Symptom Scale) were evaluated weekly and efficacy of Simvastatin and Placebo on social withdrawal, emotional withdrawal, blunted affect and other negative symptoms were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052034046N1**
Registration date: **2017-06-17, 1396/03/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-17, 1396/03/27

Registrant information

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Ahwaz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Ahwaz University of Medical Sciences, Doctor Behzad Sharif Makhmal Zadeh

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine the effect of Simvastatin to control negative symptoms of atypical antipsychotics in patients with schizophrenia

Public title

Effect of Simvastatin in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for this study: having a diagnosis of schizophrenia according to DSM-IV-TR؛ a PANSS total score of 50 or higher on the scale؛ the scale PANSS negative score of 15 or more of 70-18 years, during a period of at least 1 year of disease onset. Exclusion criteria for this study: patients with a history of sensitivity to statins ؛ active liver disease or increase stability and unexplained liver enzymes؛ kidney failure؛ medical condition serious؛ drug abuse or drug dependence during the previous month؛ pregnancy؛ lactation؛ there at the same time other psychiatric disorders requiring drug therapy؛ desire to commit suicide or homicide؛ possession of dementia and

cognitive impairment serious: unrelated to schizophrenia: organic disease of the brain such as seizures and severe mental retardation and Parkinson's disease, Taking anti psychotic oral over the past month or long-acting injections over the past three months: the concomitant use of other drugs such as antidepressants or lithium: etc. which may be a result of treatment interfere: schizophrenia resistant to treatment: lack of response to an adequate dose and appropriate for typical anti psychotic drugs.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2

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
Department of Development Research Ethics Committee of the Ahwaz University of Medical Sciences

Street address
Ahvaz University of Medical Sciences, City University, Golestan

City
Ahwaz

Postal code

Approval date
2012-05-12, 1391/02/23

Ethics committee reference number
ETH - 457

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia are generally identified by distorting the basic characteristics of thinking and perception, and affects that are inappropriate or not. Clear consciousness and intellectual capacity are usually maintained although certain cognitive deficits

Primary outcomes

1

Description
Emotional withdrawal

Timepoint
Before the study; week third; sixth week

Method of measurement
PANSS (Positive and Negative Symptom Scale)

Secondary outcomes

1

Description
Social withdrawal

Timepoint
Before the experiment three weeks after the intervention; six weeks after intervention

Method of measurement
PANSS (Positive And Negative Symptom Scale)

Intervention groups

1

Description
In the intervention group: Simvastatin Tablets, 20 mg orally, once a day for 6 weeks

Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, 20 mg oral, once a day for 6 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Psychiatry

Full name of responsible person
Somayeh Ashrafi

Street address

Golestan, City University, Ahvaz University of Medical Sciences, Psychiatric ward

City
Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Ahwaz University of Medical Sciences

Full name of responsible person
Doctor Behzad Sharif Makhmal Zadeh

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Ground Floor, Vice Chancellor for Research and Technology Development, Ahvaz University of Medical Sciences, City University, Golestan

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Ahwaz

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, Ahwaz 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
Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person
Doctor Seyed Mohammad Seyed Ghaffari Dezffooli

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Department of Psychology / Psychiatrist

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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