

# 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

ashrafi.so@ajums.ac.ir

##### 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.

##### 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

#### 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

###### Name

Somayeh Ashrafi

###### Name of organization / entity

Ahwaz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3445 6807

###### Email address

##### 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

Ahwaz 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

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

**City**  
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

**Position**  
Department of Psychology / Psychiatrist

### Other areas of specialty/work

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

**City**  
Ahwaz

### Postal code

**Phone**  
+98 61 3336 7543

### Fax

**Email**  
ashrafi.so@ajums.ac.ir

**Web page address**  
www.ajums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**  
Somayeh Ashrafi

**Position**  
Resident of Psychiatry

### Other areas of specialty/work

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

**City**  
Ahwaz

**Postal code**  
6481958956

**Phone**  
+98 61 3336 7543

### Fax

**Email**  
ashrafi.so@ajums.ac.ir ; dr.ashrafi77@gmail.com

**Web page address**  
www.ajums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahwaz Jundishapur University of Medical Sciences

**Full name of responsible person**  
Doctor Seyed Mohammad Seyed Ghaffari Dezffooli

**Position**  
Assistant Professor of Psychiatry /Psychiatrist

### Other areas of specialty/work

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

**City**  
Ahwaz

**Postal code**  
6481958956

**Phone**  
+98 61 3336 7543

### Fax

**Email**  
**Web page address**

## 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*