Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effects of add-on treatment with Atorvastatin on cognitive deficits in schizophrenic patients

Protocol summary

Study aim
Evaluation of cognitive state in schizophrenic patients before and after adding Atorvastatin to second generation antipsychotic drugs in comparison to the control group

Design
Randomised, double blind, parallel group, with intervention and control groups, clinical trial

Settings and conduct
Preparing Atorvastatin and placebo with a double-blind design (patients, evaluator, researcher) in closed packs and labeled with a code number by the pharmacologist. 64 schizophrenic patients admitted in Ebn-e Sina Hospital that fulfill the inclusion criteria

Participants/Inclusion and exclusion criteria
18 to 64 year old patients with minimum eight grade education and diagnosis of schizophrenia, with no medical, other psychiatric or substance use disorders (except cigarette), no history of major head trauma, no concomitant drugs that interact with atorvastatin, no history of serious adverse reaction to Atorvastatin, and not currently in another study, and women not pregnant or breastfeeding. In case of serious adverse reactions during this study or lack of cooperation by the patients or his/her families, they will be excluded from the study.

Intervention groups
n the intervention group, 20mg per day Atorvastatin and in the control group a placebo will be added.

Main outcome variables
Changes in positive and negative schizophrenic symptoms by Positive And Negative Symptoms Scale test and cognitive changes based on Stroop test, Wechsler test, Verbal Fluency test, Wisconsin Card Sorting test, Digit span test, and Trial Making test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190621043962N1**
Registration date: **2019-09-19, 1398/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-19, 1398/06/28**
Update count: **0**

Registration date
2019-09-19, 1398/06/28

Registrant information

Name
Zahra Soleimani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3723 4586

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drsoleimani92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of add-on treatment with Atorvastatin on cognitive deficits in schizophrenic patients

Public title
Evaluation of the effects of add-on treatment with Atorvastatin on cognitive deficits in schizophrenic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of schizophrenia based on DSM-5 patients between 18 and 64 years Informed consent by the patients and a member of his/her family Minimum eighth grade education No psychiatric comorbidity No medical comorbidity No substance use, except for cigarettes No history of hypersensitivity reaction or intolerable side effects with Atorvastatin No concomitant drugs that they interact with Atorvastatin (Anti-inflammatory drugs such as Aspirin and Ibuprofen, Thiazide diuretics, weight-loss drugs, anti-fungal drugs, Macrolids, Colchicin, Protease inhibitors) No pregnancy or breastfeeding (for women) No history of major head trauma No participation in other study in the time of this study No major cognitive deficits comorbidity
Exclusion criteria:
Failure to the patient or his/her family to continue the study Occurrence of any serious side effects during the study
Age
From **18 years** old to **64 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The form of drug and placebo are similar and the patients and evaluators are blind in regards to their study group assignment. Drug and placebo will be prepared in closed packs and labeled with specific codes by the pharmacologist.
Blinding (investigator's opinion)
Double blinded
Blinding description
The form of drug and placebo are similar and the patients and evaluators are blind in regards to their study group assignment. Drug and placebo will be prepared in closed packs and labeled with specific codes by the pharmacologist.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical science
Street address
Vice-chancellor of Research and Technology, Mashhad University of Medical Sciences, Daneshgah St, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2019-06-17, 1398/03/27
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.194

Health conditions studied

1

Description of health condition studied
schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
cognitive state
Timepoint
At the outset of the study (before intervention), at 21 days 42 days after starting Atorvastatin
Method of measurement
PANSS test, Stroop test, Digit span test, Verbal fluency test, Wechsler test, Wisconsin Card Sorting test, and Trial making test

Secondary outcomes

1

Description
positive and negative symptoms score
Timepoint
At the outset of the study (before intervention), and at 3 and 6 weeks after starting Atorvastatin
Method of measurement

Positive and Negative Symptoms Scale test

Intervention groups

1

Description
Intervention group: The intervention group will take Atorvastatin tablet (20 milligram) once daily via oral route for 6 weeks. This drug will be produced by the Pharmacology department of Mashhad University of Medical Sciences
Category
Treatment - Drugs

2

Description
Control group: The control group will take placebo tablet once daily via oral route for 6 weeks. This drug will be produced by the Pharmacology department of Mashhad University of Medical Sciences
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebn-e Sina hospital
Full name of responsible person
Zahra Soleimani
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Horre Ameli Blvd , Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Vice-chancellor of Research and Technology, Mashhad University of Medical Sciences, Daneshgah St, Mashhad
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Web page address
https://v-research.mums.ac.ir/index.php/moaven/tafaghodim
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Soleimani
Position
Assistant professor
Latest degree
Medical doctor
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of this clinical study will be published in an article

When the data will become available and for how long

The results will be accessible to public after study completion

To whom data/document is available

The results of this study will be open for public access in all national and international journals

Under which criteria data/document could be used

Files will be accessible after they are approved by the ethics committee of Mashhad University of Medical Sciences

From where data/document is obtainable

Vice-chancellor of Research and Technology, Mashhad University of Medical Sciences

What processes are involved for a request to access data/document

For access to files, you can refer to Vice-chancellor of Research and Technology of Mashhad University of Medical Sciences

Comments