

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of aspirin and simvastatin efficacy as adjuvant treatment on negative and positive symptoms and general psychopathology in patient with schizophrenia

Protocol summary

Study aim

Determining the effectiveness of aspirin and simvastatin as adjunctive therapy in hospitalized patients with schizophrenia and using treatment with greater effectiveness and fewer complications in these patients

Design

In this study, three intervention groups will be considered and patients will be randomly divided between these three groups. The design of this study in terms of blinding will be double-blind.

Settings and conduct

This study will be performed in the period of May 2021 to December 2021 in the men and women wards of Razi Psychiatric Hospital. Razi Psychiatric Hospital is one of the centers covered by the University of Social Welfare and Rehabilitation Sciences.

Participants/Inclusion and exclusion criteria

Male and female patients with schizophrenia from the age group of 18 to 60 years whose disease duration is more than 2 years and have no substance dependence or underlying disease.

Intervention groups

Individuals included in the study will be randomly divided between intervention and control groups. Groups A and B are known as the intervention group and group C as the control group. All three groups will first be treated with risperidone tablets 4-6 mg daily for 2 weeks, then group A will receive 625 mg of aspirin daily (two capsules containing 325 mg of aspirin powder prepared under the supervision of a pharmacist) and group B will receive treatment. 40 mg of simvastatin daily (two capsules containing 20 mg of simvastatin powder prepared under the supervision of a pharmacist) is added to the treatment and in the control group, placebo capsules will be used.

Main outcome variables

Adjuvant treatment of patients with schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049994N1**

Registration date: **2021-02-05, 1399/11/17**

Registration timing: **prospective**

Last update: **2021-02-05, 1399/11/17**

Update count: **0**

Registration date

2021-02-05, 1399/11/17

Registrant information

Name

Matina Pourghasem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 8929

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matinapourghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of aspirin and simvastatin efficacy as adjuvant treatment on negative and positive symptoms and general psychopathology in patient with schizophrenia

Public title

Effect of aspirin and simvastatin in schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized patients with schizophrenia who have been diagnosed for more than 2 years

Exclusion criteria:

Patients with schizophrenia with a history of physical illness such as gastrointestinal disorders

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to eliminate some possible biases in this study, randomization will be observed. In this study, a random sequence of numbers will be created using the web-based software <https://www.Randomization.com> to randomly assign individuals to three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The packaging and drug form of the capsules and placebo was similar to each other to preserve the blindness of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and

Rehabilitation

Street address

No.6 . Samani Alley. Forsat Shirazi Ave

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Tehran

Province

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1419913661

Approval date

2019-11-01, 1398/08/10

Ethics committee reference number

IR.USWR.REC.1398.130

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Comparison of aspirin and simvastatin efficacy as adjuvant treatment on negative and positive symptoms and general psychopathology in patient with schizophrenia

Timepoint

The beginning of the study, 4 and 8 weeks after taking aspirin or simvastatin

Method of measurement

Positive and Negative Symptoms Scale for Schizophrenia

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with schizophrenia that were treated by risperidone to whom 650 mg of aspirin (325 mg twice daily) will be added daily.

Category

Treatment - Drugs

2

Description

Intervention group: patients with schizophrenia that were treated by risperidone to whom 40 mg of simvastatin (20mg twice daily) will be added daily.

Category

Treatment - Drugs

3

Description

Control group: patients with schizophrenia that were treated by risperidone who will be given placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Matina Pourghasem

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available