

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Spirinolactone as an Adjuvant Therapy on Improvement of Negative Signs and Cognitive Symptoms in Schizophrenic Patients ; A randomized, double-blind clinical trial with placebo control

Protocol summary

Study aim

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of Spironolactone would improve psychopathology in subjects with schizophrenia treated with Risperidone

Design

Randomized, double-blind, placebo controlled study

Settings and conduct

The study will be conducted among patients attending Roozbeh Hospital-Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria:1-Diagnosis of Schizophrenia based on DSM-5 criteria; 2- Age between 18-50; 3-Chronic Schizophrenia- duration of the disorder more than 2 years; 4-Minimum score of 20 in negative sub score. Exclusion criteria:1-Any serious medical or neurological problem; 2- IQ less than 70; 3- Substance dependence during the last 6 months(except for nicotine and caffeine); 4- meeting the criteria of major depressive disorder 5-receiving ECT during the last 2 weeks; 6.concurrent consumption of alcohol 7- History of cardiac surgery; 8- receiving oral antipsychotic during the last week or depot antipsychotic during the last month 9.suicidality 10. hyperkalemia

Intervention groups

Tablet Risperidone (6 mg/day) combined with 100mg/day Spironolactone as intervention group for 8 weeks

Main outcome variables

Severity of schizophrenia

General information

Reason for update

just to correct a typo. Indeed, in the approved proposal was 100 mg/day

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N120**

Registration date: **2019-10-12, 1398/07/20**

Registration timing: **prospective**

Last update: **2020-09-07, 1399/06/17**

Update count: **1**

Registration date

2019-10-12, 1398/07/20

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Spirinolactone as an Adjuvant Therapy on Improvement of Negative Signs and Cognitive Symptoms in Schizophrenic Patients ; A randomized, double-blind clinical trial with placebo control

Public title

Effect of Spirinolactone in treatment of Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Schizophrenia based on DSM-5 criteria Age between 18-50 Chronic Schizophrenia- duration of the disorder more than 2 years Minimum score of 19 in negative sub score

Exclusion criteria:

Any serious medical or neurological problem IQ less than 70 Substance dependence during the last 6 months(except for nicotine and caffeine) Receiving ECT during the last 2 weeks Serum potassium more than 5 meq/L History of cardiosurgery Receiving oral antipsychotics during the last week or long-standing antipsychotic during the last month Meeting the criteria of major depressive disorder Suicidality Concurrent consumption of alcohol Pregnant or lactating women Receiving Pentoxifylline

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks (each block has four cases)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, clinicians and outcome evaluators will be blind regarding grouping

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-10-03, 1398/07/11

Ethics committee reference number

IR.TUMS.VCR.REC.1398.540

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Severity of schizophrenia

Timepoint

Baseline and weeks 2- 4- 8 after beginning of treatment

Method of measurement

by Positive and Negative Symptoms Scale

Secondary outcomes

1

Description

cognitive symptoms

Timepoint

Baseline and weeks 2- 4- 8 after beginning of treatment

Method of measurement

by MMSE

Intervention groups

1

Description

Intervention group: Tablet Risperidone (6 mg/day) combined with 100 mg/day Spironolactone as intervention group for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Tablet Risperidone (6 mg/day) combined with placebo as control group for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Psychiatry Hospital

Full name of responsible person

Dr. Şahin Akhondzadeh

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data will be distributed through final report

When the data will become available and for how long

from 2021 to 2026

To whom data/document is available

academic researchers

Under which criteria data/document could be used

by email

From where data/document is obtainable

Prof Shahin Akhondzadeh

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

s.akhond@sina.tums.ac.ir

Comments