

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Resveratrol as adjunctive therapy in the treatment of negative symptoms in patients with schizophrenia: a double blind and placebo controlled trial

Protocol summary

Study aim

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of Resveratrol 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 18-60; 3-Chronic Schizophrenia- duration of the disorder more than 2 years; 4-Minimum score of 20 in negative sub score. 5- being stable on risperidone for the last 2 months
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- Score on HDRS less than 14 5-receiving ECT during the last 3 months ; 6-Acute or chronic systemic diseases; 7- History of neurosurgery; 8- History of head trauma

Intervention groups

Tablet Risperidone (4-6 mg/day) combined with 200mg/day Resveratrol as intervention group for 8 weeks

Main outcome variables

Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N103**

Registration date: **2017-12-24, 1396/10/03**

Registration timing: **prospective**

Last update: **2017-12-24, 1396/10/03**

Update count: **0**

Registration date

2017-12-24, 1396/10/03

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

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Resveratrol as adjunctive therapy in the treatment of negative symptoms in patients with schizophrenia: a double blind and placebo controlled trial

Public title

Resveratrol in the treatment of chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Schizophrenia based on DSM-5 criteria Age between 18-60 Chronic Schizophrenia- duration of the disorder more than 2 years Minimum score of 20 in negative sub score being stable on risperidone(4 to 6 mg per day) for the last 2 months

Exclusion criteria:

Any serious medical or neurological problem IQ less than 70. Substance dependence during the last 6 months(except for nicotine and caffeine) Score on HDRS less than 14 receiving ECT during the last 3 months Acute or chronic systemic diseases History of neurosurgery History of head trauma

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-12-09, 1396/09/18

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4183

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 beginig of treatment

Method of measurement

by Positive and Negative Symptoms Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet Risperidone (4-6 mg/day) combined with 200 mg/day Resveratrol as intervention group for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Tablet Risperidone (4-6 mg/day) combined with placebo as control group for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

Street address

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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
Medical Pharmacy
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Person responsible for updating data

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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 2020 to 2025

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