

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

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

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of citicoline would improve psychopathology in subjects with schizophrenia treated with Risperidone. 50 patients with chronic schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=25) or 2500 mg/day of citicoline (N=25) for 8 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Positive and Negative Syndrome Scale (PANSS). Side effects will be also evaluated using checklist and Extra-pyramidal Symptoms Rating Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604051556N87**

Registration date: **2016-04-06, 1395/01/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-06, 1395/01/18

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

Tehran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-21, 1395/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Citicoline as adjunctive treatment of negative symptoms in patients with schizophrenia

Purpose

Treatment

Inclusion/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.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2016-02-20, 1394/12/01

Ethics committee reference number

IR.TUMS.REC.1394.2188

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

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups**1****Description**

Tablet Risperidone (6 mg/day) combined with 2500mg/day Citicoline as intervention group for 8 weeks

Category

Treatment - Drugs

2**Description**

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 Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Sreet

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Yunesian

Street address

Tehran University of Medical Sciences, Keshavarz Blvd.

City

Tehran

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

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

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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City

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