# 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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*