

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

L carnosine 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 L carnosine 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 2 gr/day of L carnosine(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: **IRCT201504211556N75**

Registration date: **2015-04-22, 1394/02/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-22, 1394/02/02

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

2015-05-22, 1394/03/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

L carnosine 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	Positive and Negative Syndrome Scale (PANSS)
Phase 3	Secondary outcomes empty
Groups that have been masked No information	Intervention groups
Sample size Target sample size: 50	<u>1</u>
Randomization (investigator's opinion) Randomized	Description Tablet Risperidone (6 mg/day) combined with placebo as control group for 8 weeks
Randomization description	Category Placebo
Blinding (investigator's opinion) Double blinded	<u>2</u>
Blinding description	Description Tablet Risperidone (6 mg/day) combined with 2 gr/day L carnosine as intervention group for 8 weeks
Placebo Used	Category Treatment - Drugs
Assignment Parallel	
Other design features	
Secondary Ids empty	Recruitment centers
Ethics committees	<u>1</u>
<u>1</u>	Recruitment center
Ethics committee	Name of recruitment center Roozbeh Hospital
Name of ethics committee Ethics Committee of Tehran University of Medical Sciences	Full name of responsible person Prof. Shahin Akhondzadeh
Street address Keshvarz Blvd	Street address South Kregar street, Roozbeh Hospital
City Tehran	City Tehran
Postal code	
Approval date 2015-04-21, 1394/02/01	
Ethics committee reference number 27749	Sponsors / Funding sources
Health conditions studied	<u>1</u>
<u>1</u>	Sponsor
Description of health condition studied schizophrenia	Name of organization / entity Tehran University of Medical Sciences
ICD-10 code F20	Full name of responsible person Dr masoud yunesian
ICD-10 code description schizophrenia	Street address Keshvarz Blvd
	City Tehran
Primary outcomes	Grant name
<u>1</u>	Grant code / Reference number
Description Severity of schizophrenia	Is the source of funding the same sponsor organization/entity? Yes
Timepoint Baseline and weeks 2-4-8 after beginig of treatment	Title of funding source Tehran University of Medical Sciences
Method of measurement	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***Postal code****Phone**

+98 21 5541 2222

Fax**Email**

s.akhond@sina.tums.ac.ir

Web page address**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**Street address**

South Kargar street; Roozbeh Hospital

City

Tehran

Postal code**Phone**

+98 21 5541 2222

Fax**Email**

s.akhond@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Tehran

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*