

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

L Carnosine added to risperidone in the treatment of Autism: A double blind and placebo controlled trial

Protocol summary

Summary

The objective of this study is to assess the efficacy of L-Carnosine in the treatment of autism. Fifty children between the ages 3 and 12 years with a DSM-5 clinical diagnosis of autistic disorder and who will be outpatients from a specialty clinic for children will be recruited. The children should present with a chief complaint of severely disruptive symptoms related to autistic disorder. Patients will be randomly allocated into L-Carnosine (800 mg/day) + Risperidone (1-3.5mg/day) or Placebo + Risperidone (1-3.5mg/day) for a 10-week, double-blind, placebo-controlled study. Patients will be assessed at baseline and after 5 and 10 weeks of starting medication. The primary outcome measure is the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritability subscale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512081556N83**

Registration date: **2015-12-09, 1394/09/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-09, 1394/09/18

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

2015-12-22, 1394/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L Carnosine added to risperidone in the treatment of Autism: A double blind and placebo controlled trial

Public title

L Carnosine in the treatment of Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-DSM-5 clinical diagnosis of autistic disorder, 2-children between the ages of 3 and 12 years, 3- presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone) Exclusion Criteria:1- Presence of any active medical problem, 2-any diagnosis in Axis I and II except for mental retardation, 3- receiving any psychotropic medications during past two weeks prior to the trial, 5-presence of hepatic disease, 6-history of seizure

Age

From **3 years** old to **12 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)**

Not 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, Ghods St., Keshvarz Blvd

City

Tehran

Postal code**Approval date**

2015-11-01, 1394/08/10

Ethics committee reference number

IR.TUMS.REC.1394.1063

Health conditions studied**1****Description of health condition studied**

Autistic Disorder

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes**1****Description**

Severity of Autism

Timepoint

Baseline and weeks 5 and 10 after beginning of treatment

Method of measurement

Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritability subscale)

Secondary outcomes

empty

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

Tablet L-Carnosine 800 mg/day+ Tablet Risperidon 1-3.5 mg/day as intervention 10 for 10 weeks

Category

Treatment - Drugs

2**Description**

Tablet Risperidone 1-3.5 mg/day +Capsule Placebo as control for 10 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, Ghods St., Keshvarz 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**Street address**

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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*