

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

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

Protocol summary

Summary

The aim of the present study is to evaluate the efficacy of L carnosine on ADHD in children and adolescents through a double-blind, randomized, controlled trial. 50 outpatients, including 6-17 years old who clearly meet the DSM-5 diagnostic criteria for ADHD(based on diagnosis of a child psychiatrist) will be randomly assigned to receive L carnosine tablets (400mg BID) and methylphenidate (0.5 to 1.5 mg per day) or methylphenidate (0.5 to 1.5 mg per day) and placebo for 8 weeks. The primary outcome measure is the Teacher and Parent ADHD Rating Scale. Patients will be assessed by a child psychiatrist at baseline, 28 and 56 days after the medication started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601031556N84**

Registration date: **2016-01-04, 1394/10/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-04, 1394/10/14

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

2016-01-21, 1394/11/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of ADHD based on DSM-5; age between 6-17 years old. Exclusion criteria: mental retardation; receiving of L carnosine during the last 3 weeks; presence of any psychiatric disorders except for ODD; history of allergy to L carnosine or Ritaline; presence of any medical problem including cardiovascular diseases; presence of uncontrolled seizures; systolic blood pressure more than 120 mm Hg; resting pulse rate less than 60/minute or more than 115/minute; receiving any supplement or medication for ADHD.

Age

From **6 years** old to **17 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

Keshvarz Blvd

City

Tehran

Postal code**Approval date**

2015-12-22, 1394/10/01

Ethics committee reference number

IR.TUMS.REC.1394.1290

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

Disturbance of activity and attention

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

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

Severity of ADHD

Timepoint

Week 0 (before treatment) and Weeks 4 and 8 after

treatment

Method of measurement

Teacher and Parent ADHD Rating Scale

Secondary outcomes

empty

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

Tablet L- carnosine 400 mg BID and Ritaline 0.5 to 1.5 mg per day as intervention group for 8 weeks

Category

Treatment - Drugs

2**Description**

Ritaline 0.5 to 1.5 mg per day and 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

South Kargar Sreet, Roozbeh Hospital

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, 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

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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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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