Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 duiagnosis 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
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Iran (Islamic Republic of)
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+98 21 5541 2222
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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 Sreeet, 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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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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