Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

L-Carnitine as an adjuvant therapy in the treatment of autism in children: randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim
Investigating the effect of L-Carnitine for the treatment of autism

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be conducted among children with autistic disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: DSM-5 clinical diagnosis of autistic disorder - Children between the ages of 5 and 11 years - Having a minimum score of 12 in irritability. Exclusion criteria: Presence of any psychiatric disorder - History of allergy to medications used in this research - Presence of any active medical problem such as heart disease - History of uncontrolled seizure - Receiving any psychotropic medications except risperidone during past two weeks prior to the trial

Intervention groups
Intervention group: Patients treated with risperidone 1-3mg per day and L-Carnitine 50mg/kg per day. Control group: Patients treated with risperidone 1-3mg per day and placebo.

Main outcome variables
Severity of autism

General information

Reason for update
There was a typo regarding the dose of L-Canitine that I corrected it

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N136**
Registration date: **2021-05-03, 1400/02/13**
Registration timing: **prospective**
Last update: **2023-01-06, 1401/10/16**
Update count: **1**

Registration date
2021-05-03, 1400/02/13

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

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
L-Carnitine as an adjuvant therapy in the treatment of autism in children: randomized double blind and placebo controlled clinical trial

Public title
L-Carnitine for the treatment of autism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

DSM-5 clinical diagnosis of autistic disorder Children between the ages of 5 and 11 years Having a minimum score of 12 in irritability

Exclusion criteria:

Presence of any psychiatric disorder History of allergy to medications used in this research Presence of any active medical problem such as heart disease History of uncontrolled seizure Receiving any psychotropic medications except risperidone during past two weeks prior to the trial

Age

From **5 years** old to **11 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

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, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.TUMS.DDRI.REC.1399.051

Health conditions studied

1

Description of health condition studied

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Severity of autism

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community (ABC-C) and Childhood autism rating scale (CARS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients treated with risperidone 1-3mg per day and L-Carnitine 150mg/kg per day.

Category

Treatment - Drugs

2

Description

Control group: Patients treated with risperidone 1-3mg per day and placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh hospital

Full name of responsible person
Prof. Mohammad Reza Mohammadi

Street address
Roozbeh Hospital, South Kargar Street

City
Tehran

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1333715914

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+98 21 5541 2222

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mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraian

Street address
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msahrai@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Shahin Akhondzadeh

Position
Professor of clinical psychopharmacology

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data will be distributed through final report
When the data will become available and for how long
5 years from 2022 to 2027
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Users should cite the resource of data
From where data/document is obtainable
Prof Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments