

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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-Carnitine 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**

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**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

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

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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

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

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**Email**

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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### Person responsible for updating data

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**Email**

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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**