

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of the effect of Citicoline on the cognitive-behavioral performance of autism spectrum patients with standard treatments

Protocol summary

Study aim

Comparison of the effect of citicoline on the cognitive and behavioral performance of autism spectrum patients referred to Imam Reza Clinic in Shiraz with standard treatments.

Design

The statistical population includes all child patients (less than 18 years old) suffering from autism spectrum disorders who refer to Imam Reza Clinic in Shiraz. The control group of children with autism who receive standard treatments including the neuroleptic drug Risperidone, Piracetam and Omega 3, and the second group receives citicoline drug in addition to the neuroleptic drug. Considering the number of 37 people for each group was determined as the sample size. Finally, considering a 10% drop, at least 41 people were considered for each group. Due to the fact that the population of autistic patients refer to Imam Reza clinic therefore, the census method is used to determine the sample size.

Settings and conduct

All patients will be examined by pediatric neurologists, and patient information including demographic information and findings related to the progress or treatment of autism spectrum disorder will be collected in special forms.

Participants/Inclusion and exclusion criteria

The statistical includes all child patients (less than 18 years old) suffering from autism spectrum disorders who refer to Imam Reza Clinic in Shiraz. Inclusion criteria: Primary diagnosis of autism using MCHAT test in children under 3 years old and CARS test in children over 3 years old. Exclusion criteria: Intractable seizures, high blood pressure, underlying diseases such as diabetes and asthma, and lack of parental consent to enter the study.

Intervention groups

Intramuscular injection of citicoline drug in the form of 10 mg/kg twice a week for one month and after one month of drug injection, initial tests are completed by

the patient.

Main outcome variables

Finding a new drug to treat autism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231030059898N1**

Registration date: **2023-11-08, 1402/08/17**

Registration timing: **prospective**

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Samaneh Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4298

Email address

stud2500025152@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-01-11, 1402/10/21

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of the effect of Citicoline on the cognitive-behavioral performance of autism spectrum patients with standard treatments

Public title
Comparison of the effect of Citicoline on the cognitive-behavioral performance of autism spectrum patients with standard treatments

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Primary diagnosis of autism using MCHAT test in children under 3 years old and CARS test in children over 3 years old

Exclusion criteria:
Intractable seizures, high blood pressure, underlying diseases such as diabetes and asthma, and lack of parental consent to enter the study

Age
To **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation method in this study will be the random permutation block method of 4 such that A represents a person who receives standard treatments and citicoline and B represents a person who receives only standard treatments. This method considering blocks of six so that the total number of possible permutations of six is equal to 6 includes: ABAB, BABA, AABB, BBAA and ABBA, BAAB. Then, by using the table of random numbers and assigning a code from 0 to 9 to each of the permutations, the desired random list of 80 items, which includes 20 blocks of 4 items ($4 \times 20 = 80$ total number of samples) is generated and the order of allocation Each of the methods is specified for each of the samples participating in the study.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The specialized committee of ethics in biomedical research

Street address

central building of Shiraz University of Medical Sciences, in front of Palestine Street, Zand Street, Shiraz

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2023-10-16, 1402/07/24

Ethics committee reference number

IR.SUMS.MED.REC.1402.325

Health conditions studied

1

Description of health condition studied

Autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

MCHAT test score for under 3 years old and CARS test for over 3 years old

Timepoint

The beginning of the study and 2 months later

Method of measurement

MCHAT test for under 3 years old and CARS test for over 3 years old

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intramuscular injection of citicoline along with standard treatments to 40 people under the

age of 18 with autism.

Category

Treatment - Drugs

2

Description

Control group: receiving standard treatments by 40 patients with autism

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza specialized and sub specialized clinic

Full name of responsible person

Razieh Taghizade Sarvestani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempour

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Shiraz, Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Razieh Taghizade Sarvestani

Position

assistant professor

Latest degree

Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable