

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the efficacy of memantine in improvement of behavioral disorders and electroencephalographic findings in children with autistic spectrum disorder aged 4-12 years old

Protocol summary

Study aim

Evaluation of the efficacy of memantine in the improvement of behavioural disorders and electroencephalographic findings in children with autistic spectrum disorder

Design

Two arms parallel-group randomized trial single-blind, on 52 participants using simple randomization.

Settings and conduct

Patients who refer to imam Reza clinic of shiraz university of medical science and diagnosed with autism based on DSM 5 and, using GARS questionnaire aged between 4 - 12 years old with normal EEG would be entered into the study and would fill out ABC questionnaire and receive their treatment according to their group of intervention. After 10 weeks patients would repeat their EEG test and fill out the ABC questionnaire again.

Participants/Inclusion and exclusion criteria

- Patients diagnosed with ASD according to DSM 5 - Patients with no previous history of epilepsy and/or abnormal electroencephalography - Patients aged between 4 to 12 years old

Intervention groups

There would be two parallel-group: 1. This group would be patients receiving the normal treatment (risperidone) 2. The second group would be the intervention group that receive memantine as an adjunct treatment (risperidone + memantine)

Main outcome variables

1. ABC questionnaire scores and results 2. EEG analysis and changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211118053097N1**

Registration date: **2022-03-26, 1401/01/06**

Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**

Update count: **0**

Registration date

2022-03-26, 1401/01/06

Registrant information

Name

Hossein Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3235 5576

Email address

hbayat@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of memantine in improvement of behavioral disorders and electroencephalographic

findings in children with autistic spectrum disorder aged 4-12 years old

Public title

An investigation on the effect of memantine on children with autistic spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with ASD according to DSM 5 Patients with no previous history of epilepsy and/or abnormal electroencephalography Patients aged between 4 to 12 years old

Exclusion criteria:

Intolerance to Memantine Patients and/or their caregiver's disinclination to continuing with trial

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups is done using a random number table. After specifying the statistical population, each participant is given a two-digit code, and a row or a column of the random number table is randomly assigned. Select and continue in the same direction. In this way, the group of intervention or control is determined. Then, due to the two-sided blindness of the study, the necessary treatment is given for each group. Participants are entered into the study by a psychiatrist. Determining the random allocation sequence and the list of intervention and control groups will be done by the statistical consultant and SPSS software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-sided blind study and the main researchers, the Data and Safety Monitoring Board, have information about the type of drugs used and the grouping of all the individuals. Participants in the project do not know the type and specifications of the drug used and the drugs would be provided by their caregivers. Evaluators are aware of the type of grouping of individuals.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of shiraz University of Medical Sciences

Street address

Zand St., Shiraz, Iran

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2021-09-07, 1400/06/16

Ethics committee reference number

IR.SUMS.MED.REC.1400.298

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

patients diagnosed with ASD

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

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

Electroencephalography analysis

Timepoint

Before the treatment and 10 weeks after treatment onset

Method of measurement

Using the Electroencephalograph and analysis of activities

2**Description**

ABC questionnaire (measuring cognitive activity)

Timepoint

Before the treatment and 10 weeks after treatment onset

Method of measurement

Filling ABC autism questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group 1 would receive risperidone with 0.25 mg/ daily initiation dose for under 20kg weight and 0.5mg/daily for above 20kg. they would also receive memantine (□ Osvah Pharmaceutical Co.) with 5 mg/daily initial dose and 5mg/weekly increasing dose until reaching 15mg/daily for children weighted between 10 to 40 kg and for above 40kg 20mg/daily.

Category

Treatment - Drugs

2

Description

Control group: group 2 would receive risperidone with 0.25 mg/ daily initiation dose for under 20kg weight and 0.5mg/daily for above 20kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Pegah Katibeh

Street address

Namazi Sq, Shiraz, Fars.

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Email

emamreza@sums.ac.ir

Web page address

<https://emamreza.sums.ac.ir/page-EmamRezaClinic1/f>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Street address

Zand st, Shiraz, Fars.

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 21 3230 5410

Fax

Email

info@sums.ac.ir

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

50

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

Narjes Raja-beheshti

Position

fellowship student

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Imam Reza Clinic, Namazi Sq, Shiraz, Fars.

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Email

Narjesrb@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Pegah Katibeh

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Imam Reza Clinic, Namazi Sq, Shiraz, Fars.

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Fax

Email

pegahkatibeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hossein Bayat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

Street address

Shiraz University of Medical Science, Zand blvd

City

Shiraz

Province

Fars

Postal code

71354664546

Phone

+98 71 3235 5576

Fax

Email

hbayat@sums.ac.ir

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

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

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

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining confidentiality.

When the data will become available and for how long

De-identified data will be available starting 1 year after publication with permission of the research department of shiraz university of medical science.

To whom data/document is available

Academics employed at various research/university institutions and affiliated industries receiving permission from the research office of shiraz university of medical science.

Under which criteria data/document could be used

For Academic and research goals only.

From where data/document is obtainable

Narjesrb@gmail.com, Imam Reza clinic, Namazi sq, shiraz. Narjes raja-Beheshti

What processes are involved for a request to access data/document

The applicant would be asked to provide a formal request letter containing the importance of the data and the project processes with a permission letter from the research office of shiraz university of medical science. Following the receipt of the request letter, the data would be provided maxim within 1 month.

Comments