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)

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+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 trail
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, theData 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
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7134814734
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Email
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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.
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+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
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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

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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

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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

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