Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

evaluation of the effect of Donepezil in comparison with dual combination of Donepezil and Betahistine in improvement of children with autism spectrum disorder - a randomized clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of Donpezil with combination therapy of betahistine (histamine H3 receptor antagonist) and donepezil (acetylcholinesterase inhibitor) in improving the symptoms of children with autism spectrum disorder

Design

This study is a double-blind clinical trial. In this study, 34 children with ASD who were referred to the pediatric clinic of Roozbeh Hospital were randomly divided into two groups. One group is treated with donepezil (along with previous drugs) for 10 weeks and the other group is treated with a combination of betahistine and donepezil. All patients before, during the study and after the intervention were evaluated by PedsQL, SRS-2, ABC-2 tests and the results were analyzed by SPSS program.

Settings and conduct

After being visited in the clinic, patients receive their medications from the researcher depending on which group they belong to, and take new medications for 10 weeks in addition to the previous treatment regimen. Patients' symptoms are compared by 3 questionnaires mentioned in the hospital at the beginning of the study, in the half and after the end of the study.

Participants/Inclusion and exclusion criteria

inclusion criteria: children and adolescents aged 6-18 years with confirmed diagnosis of ASD No change in pharmacologic treatment was done at least for the past 4 weeks Exclusion criteria: Patients with a concomitant genetic disorder, seizure or medical illness. Patients with very severe autism disorder who may need to change the medication

Intervention groups

The participants are randomly divided into two groups of 17 people (A and B). Group A is treated with donepezil for 10 weeks and Group B is treated with the combination of donepezil and betahistine for 4 weeks along with previous drugs.

Main outcome variables

SRS questionnaire total score ABC-2 questionnaire total score PedsQL questionnaire total score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160905029714N2**
Registration date: **2022-03-08, 1400/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-08, 1400/12/17**
Update count: **0**

Registration date

2022-03-08, 1400/12/17

Registrant information

Name

Elnaz Chohedri

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
evaluation of the effect of Donepezil in comparison with dual combination of Donepezil and Betahistine in improvement of children with autism spectrum disorder - a randomized clinical trial

Public title
evaluation of the effect dual combination of Donepezil and Betahistine in improving the symptoms of autism spectrum disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All children and adolescents aged 6-18 years with autism spectrum disorder whose diagnosis has been confirmed by a child and adolescent psychiatrist. Patients in a relative remission over the past 4 weeks and no dose adjustment was required. If there is other comorbid psychiatric disorders, they should be controlled and not in the acute phase of the disease
Exclusion criteria:
If there is a concomitant genetic disorder, seizure or medical illness, these people will be excluded from the study If comorbid psychiatric disorders recur during the study, the individuals will be excluded from the study. Patients who change their medication regimen or dose during the 4 weeks before the start of the trial or during the entire trial period will also be excluded from the study Patients who do not tolerate the intended dose or experience a serious complication will be excluded from the study.
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple randomization method is used, in which 30 pockets (according to the number of participants) are placed on the table. Each pocket contains one of the two drug combinations (A or B). Participants randomly select one pocket and will be placed in that group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committees of School of Medicine - Tehran University of Medical Sciences
Street address
Office of the Vice Chancellor for Research, 1st floor ,Building No.1, Poursina St. ,Ghods St. , Enghelab St , Tehran
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2021-11-16, 1400/08/25
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.940

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
Social responsiveness score in SRS-2 questionnaire
Timepoint
Week 0(before intervention), week 5, week 10(after finishing intervention)
Method of measurement
Social Responsiveness Scale (SRS-2 questionnaire)

2

Description
scale of behavioral disturbance in Aberrant Behavior Checklist (ABC-2)
Timepoint
Week 0(before intervention), week 5, week 10(after

finishing intervention)

Method of measurement

ABC-2 questionnaire

Secondary outcomes

1

Description

PedsQL total score

Timepoint

Week 0, week 5 , week 10

Method of measurement

PedsQL questionnaire parent form

Intervention groups

1

Description

Intervention group:17 patients will be received a combination of donepezil and betahistine along with their other previous medications. Starting with 2.5mg/day in the first week and then Increase to 5 mg/day in the next 4 weeks and if it is tolerated and no side effects was seen, increase to 7.5mg/day in the sixth week and finally 10 mg/day in the last 4 weeks. The dose of betahistine used in this study is 16 mg twice daily for weight less than 50 kg and the dose of 24 mg twice daily for weights over 50 kg. Children will receive 4mg twice a day in the first week and 8mg twice a day in the second week, and if the drug is tolerable and there are no side effects, the dose will be increased to 16mg twice a day from the third week. For children over 50 kg, these doses will be 8, 16 and 24mg twice a day.

Category

Treatment - Drugs

2

Description

Control group: 17 patients will be received donepezil for 10 weeks along with other previous medications. Dosage for donepezil is 2.5 mg in the first week, 5 mg in the second to fifth week for 4 weeks, increase to 7.5 mg in the sixth week and in case of tolerance and no side effects, increase to a dose of 10md/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Alaghband rad Javad

Street address

Roozbeh hospital., South Karegar St., Tehran town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Fotouhi Akbar

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Vice Chancellor for Research and Technology, 6th floor, Central University Organization, corner of Qods St, Keshavarz Blvd

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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

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

Chohedri Elnaz

Position

Assistant of Child and adolescent psychiatry of Tehran University of Medical Sciences

Latest degree
Specialist
Other areas of specialty/work
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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
No - There is not 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
Not applicable
Data Dictionary
Not applicable