

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Assessment the efficacy of augmentation donepezil to risperidon in treatment of autism spectrum disorders

Protocol summary

Summary

(1) Objectives: Assessment the efficacy of augmentation Donepezil to risperidon in treatment of autism spectrum disorders. (2) Participants including major eligibility criteria: Eligible patients after gaining the consent of a parent or legal guardian patients will be enrolled. Patients who had organic disease, patients have been treated with other psychotropic drugs and also patients with other psychiatric disorders are excluded (3) Autism spectrum disorders 6-17 years old, The samples were randomly divided into two groups of 33 persons.(4) Intervention: Both groups were treated with Risperidone prior to entering the study, first group is treated with placebo and the second group is treated with Donepezil, Patients at weeks zero, six, twelve in terms of therapeutic effects and adverse drug reactions are evaluated. Results of the study will be assessed by CARS and check list of drugs side effects (5) Main outcome measures (variables): Severity of Autism

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041333406N1**

Registration date: **2017-09-20, 1396/06/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-20, 1396/06/29

Registrant information

Name

Neda Ghanei

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the efficacy of augmentation donepezil to risperidon in treatment of autism spectrum disorders

Public title

The efficacy of augmentation Donepezil to risperidon in treatment of autism spectrum disorders

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: Of all patients with ASD, ranging in age from 6 to 17years; Parent's Consent; No obvious organic disease; The lack of other psychiatric disorders; Not taking other psychoactive medications other than risperidone; IQ higher than 50 on the basis of Weiland test. The exclusion criteria: In the absence of cooperation of parents after inclusion; the risk of any side effect or another disease that cause a problem in results.

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of Mashhad University of Medical Sciences

Street address

Qoreishi Building, Daneshgah St

City

Mashhad

Postal code

1394491388

Approval date

2016-01-20, 1394/10/30

Ethics committee reference number

IR.MUMS.fm.REC.1394.529

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

Autism Spectrum Disorders

ICD-10 code

F84

ICD-10 code description

Pervasive developmental disorders

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

Response to treatment

Timepoint

Previous the syudy, 6 weeks after study, 12 weeks after study

Method of measurement

CARS test

2**Description**

Severity of Autism

Timepoint

Previous the syudy, 6 weeks after study, 12 weeks after study.

Method of measurement

CARS test

Secondary outcomes**1****Description**

Drug's side effect

Timepoint

Previous the study, 6weeks after study, 12weeks after study

Method of measurement

Check list

Intervention groups**1****Description**

The intervention group have been treated with risperidone(maximum dose 2 mg) is also treated with placebo. The duration of intervention is 12 weeks.

Category

Placebo

2**Description**

The intervention group have been treated with risperidone (maximum dose 2mg), is also treated with Donepezil . Dosing and titration of the drug individually, but the initial dose of Donepezil is2.5 mg and the maximum dosage is 10mg,(PO) and the duration of intervention is 12weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Outpatient Clinic

Full name of responsible person

Dr Neda Ghanei

Street address

Hore ameli boulevard-Ibne Sina Hospital
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Mashhad University of
Medical Sciences
Full name of responsible person
Dr Mahyar Mirheydari
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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

Vice Chancellor for Research of Mashhad University of
Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty