

# 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

+98 51 3711 2721

##### Email address

ghanein931@mums.ac.ir

##### 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**  
Mashhad

## 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  
**Street address**  
Qoreishi Building, Daneshgah St  
**City**  
Mashhad

#### 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

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Neda Ghanei  
**Position**  
Psychiatric Resident  
**Other areas of specialty/work**  
**Street address**  
Hore ameli boulevard\_Ibn e Sina Hospital  
**City**  
Mashhad  
**Postal code**  
**Phone**  
+98 51 3711 2721  
**Fax**  
**Email**  
ghanein931@mums.ac.irneda\_ghanei@yahoo.com  
**Web page address**

## Person responsible for scientific

## inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
dr Fateme Behdani  
**Position**  
Professor  
**Other areas of specialty/work**  
**Street address**  
Hore ameli bouleverad- ibne sina Hospital  
**City**  
Mashhad  
**Postal code**  
**Phone**  
+98 51 3711 2722  
**Fax**  
**Email**  
behdanif@mums.ac.ir  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Neda Ghanei  
**Position**  
Psychiatric Resident  
**Other areas of specialty/work**  
**Street address**  
Hore ameli boulevard-Ibn e Sina Hospital  
**City**  
Mashhad  
**Postal code**  
**Phone**  
+98 51 3711 2722  
**Fax**  
**Email**  
ghanein931@mums.ac.irneda\_ghanei@yahoo.com  
**Web page address**

## 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*