

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluating the efficacy of adding N-Acetyl cysteine to risperidone treatment regimen in patients with autism spectrum disorder

Protocol summary

Study aim

Evaluating the efficacy of adding N-Acetyl cysteine to risperidone treatment regimen in patients with autism spectrum disorder

Design

This study is a phase 3 clinical trial with a control group, with parallel, double-blind, randomized. Total of 66 ASD children who were selected from the population of by convenience sampling method and eligible patients will enter the study after a diagnostic interview. Samples will be randomly assigned to each group and divided into two groups with 33 individuals.

Settings and conduct

Research subjects included patients with ASD who referred to pediatric psychiatric clinics at Dr. Sheikh and Ibn Sina hospitals and private practice. One group is treated with risperidone and placebo tablets and the other group is treated with risperidone and n-acetylcysteine tablets. The maximum dose used is risperidone 1.5 mg daily and n-acetylcysteine 600 mg daily. The study will be evaluated by a CARS and CGI questionnaire during the study. The treating psychiatrist, psychiatric assistant evaluating the results, and the patient are unaware of the type of drug administered

Participants/Inclusion and exclusion criteria

ASD patients aging between 3 and 12 who their parents take the informed consent will enter the study. These children will not have any psychiatric or organic illness and have IQ score greater than 50; patients who their parents refuse to cooperate for any reason, using any other psychiatric drugs except risperidone or having any drug side effects which will confer with study results will be excluded.

Intervention groups

In addition to risperidone therapy provided for study participants, the intervention group will receive N-acetylcysteine (600 mg) for 10 weeks.

Main outcome variables

Regimens in patients with autism spectrum disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044199N1**

Registration date: **2019-11-10, 1398/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name

Parisa Pakravan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3661 6621

Email address

pakravanp961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of adding N-Acetyl cysteine to risperidone treatment regimen in patients with autism spectrum disorder

Public title

Efficacy of N-Acetyl cysteine in patients with autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Autism spectrum disorder (ASD) patients aging between 3 to 12 Having parental informed consent IQ score greater than 50 based on Wildland Test Receiving risperidone therapy for at least one month Lack of clear organic disease (based on family history and medical records) Clear organic causes include visual and hearing impairment, seizures, trauma cycles, chronic or acute medical disorder, and brain dysfunction. Psychiatric disorders including Toure's syndrome, Fragile X syndrome, schizophrenia, Attention deficit hyperactivity disorder (ADHD) based on structured psychiatric interview conducted by pediatric psychiatrist

Exclusion criteria:

If the parents do not cooperate for any reason after entering the study 2- 3- Use of any psychotropic drugs other than risperidone Any unbearable or life-threatening drug side effect or any other illness that requires medication which may interfere with results of this study.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Sixty-six ASD children will be selected by convenience sampling population. Eligible patients will be included in the diagnostic interview. Samples will be randomly assigned to each group and divided into two groups of 33 individuals.

Blinding (investigator's opinion)

Double blinded

Blinding description

The psychiatrist, the psychiatric assistant evaluating the results, and the patient are unaware of the type of medication prescribed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad University of Medical Sciences

Street address

Ethics Committee on Research, Quraishi Building,daneshgah str, Mashhad, Iran.

City

mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2019-06-22, 1398/04/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.212

Health conditions studied

1

Description of health condition studied

Autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

Severity of ASD was evaluated by CARS questionnaire

Timepoint

Baseline, 5 and 10 weeks after baseline

Method of measurement

CARS questionnaires

2

Description

Severity, drug response and drug adverse effects was evaluated by CGI questionnaire

Timepoint

Baseline, 5 and 10 weeks after baseline

Method of measurement

CGI questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Case group: 33 patients treated with risperidone tablets with a maximum dose of 1.5 mg daily and n-acetylcysteine tablets 600 mg daily

Category

Treatment - Drugs

2

Description

Control group: 33 patients treated with risperidone tablets with a maximum dose of 1.5 mg daily and placebo pills daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric psychiatric clinics of Doctor Sheikh and Ibn Sina Hospitals and private psychiatric clinic

Full name of responsible person

Hebrani Paria

Street address

Ibne-sina Hospital, Buali square, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

919583134

Phone

+98 51 3711 2701

Email

hebranip@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Science University of Mashhad

Full name of responsible person

Hebrani Paria

Street address

Ibne-sina hospital, Buali square, Mashhad, Iran

City

Mashhad

Province

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+98 51 3711 2701

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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

Medical Science University of Mashhad

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

Mashhad University of Medical Sciences

Full name of responsible person

Pakravan Parisa

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Ibne-sina hospital, Buali square, Mashhad, Iran.

City

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Email

pakravanp961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hebrani Paria

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Pakravan Parisa

Position

Resident

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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

Undecided - It is not yet known if there will be 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