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 eligable 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 respridone 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 corporate 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, Attension 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
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919583134
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+98 51 3711 2701
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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
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Province
Razavi Khorasan
Postal code
919583134
Phone
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Email
hebranip@mums.ac.ir
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
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Ibne-sina hospital, Buali square, Mashhad, Iran.
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Person responsible for scientific inquiries

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Position
Associate professor
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Subspecialist
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Person responsible for updating data

Contact

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Psychiatrics

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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