

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Folinic acid add on therapy to risperidone in symptoms of children with autism: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim

The objective of this study is to assess the efficacy of folinic acid in the treatment of autism

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be conducted among children with autistic disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: DSM-5 clinical diagnosis of autistic disorder children between the ages of 4 and 12 years; presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone). Exclusion criteria: presence of any active medical problem other psychiatric diagnosis except for mild to moderate intellectual disability; receiving any antipsychotic medications during past month prior to the trial; severe hepatic disease; history of allergy to risperidone and intolerance of it; history of seizure requiring change of antiepileptic dose during the last month; seizure during the last 6 months.

Intervention groups

The participants will be randomly allocated into two groups. Intervention group(25 persons) will receive folinic acid(2 mg/kg up to 50 mg per day) and risperidone (1 to 3.5 mg per day) and control group(25 persons) will receive risperidone(1 to 3.5 mg per day) for 10 weeks.

Main outcome variables

severity of autism

General information

Reason for update

change age

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N114**

Registration date: **2018-11-15, 1397/08/24**

Registration timing: **prospective**

Last update: **2020-03-22, 1399/01/03**

Update count: **1**

Registration date

2018-11-15, 1397/08/24

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Folinic acid add on therapy to risperidone in symptoms of children with autism: a randomized double-blind placebo-controlled clinical trial

Public title

Folinic acid in the treatment of autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

DSM-5 clinical diagnosis of autistic disorder Children between the ages of 4 and 12 years old Presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone)

Exclusion criteria:

Presence of any active medical problem Other psychiatric diagnosis except for mild to moderate Intellectual disability Receiving any antipsychotic medications during past month prior to the trial Severe hepatic disease History of allergy to risperidone and intolerance of it History of seizure requiring change of antiepileptic dose during the last month Seizure during the last 6 months

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permuted block

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, clinicians and outcome raters will be blind regarding grouping

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.TUMS.VCR.REC.1397.503

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

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

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

Severity of autism

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community(ABC-C) and Childhood Autism Rating scale(CARS)

Secondary outcomes

empty

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

Intervention group: Tab letfolinic acid(2mg/kg per day up to 50 mg/day) plus Risperidone (1 to 3.5 mg per day) for 12 weeks

Category

Treatment - Drugs

2**Description**

Control group: Tablet placebo plus Risperidone(1 to 3.5 mg per day) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. M.R. Mohammadi

Street address

Roozbeh Hospital, South Kargar Street,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

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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

Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2021 to 2026

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

by citing the resource

From where data/document is obtainable

Professor Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

Comments