Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Double blind randomized controlled clinical trial of the effect of short-term co-administration of acid folic on children and adolescents with autism

Protocol summary

Summary

This randomized double blind clinical trial examines the adjuvant effect of acid folic for treating irritability in children with autism. 40 children will be randomly allocated into treatment group or placebo group. Both groups will receive risperidone for 8 weeks. Outcome will be assessed using Aberrant Behavior Checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402043930N33**
Registration date: **2014-08-16, 1393/05/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-16, 1393/05/25

Registrant information

Name
Ahmad Ghanizadeh
Name of organization / entity
Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sceinces

Expected recruitment start date

2014-02-03, 1392/11/14

Expected recruitment end date

2015-02-03, 1393/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind randomized controlled clinical trial of the effect of short-term co-administration of acid folic on children and adolescents with autism

Public title

short-term co-administration of acid folicfor treating children and adolescents with autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Autism according to DSM-IV diagnostic criteria; aged 3 to 19 years old. Exclusion Criteria: primary diagnosis of a psychotic disorder; active substance abuse or dependence; unstable medical condition.

Age

From **3 years** old to **19 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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
Ethics Committee of Shiraz University of Medical Sceinces
Street address
Shiraz University of Medical Sceinces
City
Shiraz
Postal code
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Approval date
2014-02-02, 1392/11/13
Ethics committee reference number
CT-92-6478

Health conditions studied

1

Description of health condition studied
Pervasive developmental disorders
ICD-10 code
F84.0
ICD-10 code description
Childhood autism

Primary outcomes

1

Description
irritability
Timepoint
Every 4 weeks
Method of measurement
Abbrant Behavior Checklist

Secondary outcomes

1

Description
Adverse effects
Timepoint
Week 2, 4, and 8
Method of measurement
checklist

Intervention groups

1

Description
Acid folic (5mg/day)+ risperidone (0.5 to 3 mg/day)
Category
Treatment - Drugs

2

Description
Placebo + risperidone (0.5 to 3 mg/day)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences
Full name of responsible person
Ahmad Ghanizadeh
Street address
Hafez Hospital
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical sciences
Full name of responsible person
Basi Hasemi
Street address
Shiraz University of Medical Sciences
City
Fars
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, Shiraz 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
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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