Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized double blind placebo controlled clinical trial of buspirone for treating autism spectrum disorders

Protocol summary

Summary

There are some published case reports that buspirone is effective for treating some symptoms of autism. 40 children and adolescents with autism are allocated to one of the two groups. One group will receive buspirone (up to 20 mg/day) and the other group will receive placebo. Both groups will receive risperidone for 8 weeks. Irritability as the outcome will be assessed using Aberrant Behavior Checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307303930N28**
Registration date: **2014-04-04, 1393/01/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-04, 1393/01/15

Registrant information

Name

Ahmad Ghanizadeh

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 3070

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sceinces

Expected recruitment start date

2012-12-05, 1391/09/15

Expected recruitment end date

2013-12-06, 1392/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized double blind placebo controlled clinical trial of buspirone for treating autism spectrum disorders

Public title

A randomized double blind placebo controlled clinical trial of buspirone for treating autism spectrum disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: DSM-IV diagnosis of autism spectrum disorders; both genders; aged 4 to 17 years. Exclusion Criteria: a psychosis; and active substance abuse or dependency.

Age

From **4 years** old to **17 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
Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences
City
Shiraz
Postal code
Approval date
2012-12-04, 1391/09/14
Ethics committee reference number
CT-P-91-4704

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
Abbrant Behavior Checklist- irritability subscale
Timepoint
Every 4 weeks
Method of measurement
Interveiw

Secondary outcomes

1

Description
Adverse effects
Timepoint
every 4 weeks
Method of measurement
checklist

Intervention groups

1

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

2

Description
risperidone (0.5 to 3 mg/day)+ Buspirone (10 to 20 mg/day)
Category
Treatment - Drugs

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
Shiraz University of Medical sciences
Full name of responsible person
Gholam Reza Hatam
Street address
Hafez Hospital
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

Name of organization / entity
Shiraz University of Medical Sciences
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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