

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Aripiprazole versus risperidone for treatment of autism

Protocol summary

Summary

This is a double blind randomized controlled clinical trial comparing the efficacy and safety of aripiperazole (2-15mg/day), or risperidone (0.5-3mg/day) for treatment of children and adolescents with autism spectrum disorders. Diagnoses are made using DSM-IV diagnostic criteria. The study includes at least 50 children and adolescent. The duration of study is 8 weeks. Clinical Global Impression, Severity and Aberrant Behavior Checklist are used to evaluate treatment outcome. Side effects are assessed using a checklist. Assessment is one at baseline, and weeks of 4 and 8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110233930N15**

Registration date: **2011-12-12, 1390/09/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-12, 1390/09/21

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

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Aripiprazole versus risperidone for treatment of autism

Public title

Aripiprazole versus risperidone for treatment of autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: DSM-IV diagnosis of autism spectrum disorders; both genders; being able to eat medication; providing written informed consent. Exclusion Criteria: unstable medical condition; evidence of active liver disease; unstable hypertension or cardiac disease; unstable asthma; and kidney disease as determined by the investigator; subjects who are allergic to the medications; initiation of new behavioral therapy.

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not 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

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

CT-90-3135

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 Checklis

Timepoint

every 4 week

Method of measurement

interview

Secondary outcomes

1

Description

adverse effects

Timepoint

every 4 week

Method of measurement

interview

Intervention groups

1

Description

aripiperazole (2-15mg/day)

Category

Treatment - Drugs

2

Description

risperidone (0.5-3mg/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

Aliakbar Sahraeizadeh

Street address

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

Gholam Reza Hatam

Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

City

Shiraz

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***Postal code****Phone**

+98 71 1627 3070

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Web page address**Person responsible for general inquiries****Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical sciences

Full name of responsible person

Ahmad Ghanizadeh

Position

MD

Other areas of specialty/work**Street address**

Hafez Hospital, Chamran street

City

Shiraz

Person responsible for updating data**Contact****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*