

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Aripiprazole versus risperidone in the treatment of children and adolescents with tic disorders, a double blind randomized controlled clinical trial

Protocol summary

Summary

This is a 8-week, double blind, controlled clinical trial including 60 children and adolescents with tic disorder. They will be randomly allocated into one of the two groups of risperidone (0.5 to 3 mg/day) or aripiprazole (2 to 10 mg/day). DSM-IV diagnostic criteria are used to make diagnosis. YGTS and Clinical Global Impression-Severity will be used to rate the efficacy of treatment. Adverse effects are assessed using a checklist. Those with a sever medical condition are not included.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301053930N17**
Registration date: **2013-02-08, 1391/11/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-08, 1391/11/20

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

ghanizad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-31, 1391/06/10

Expected recruitment end date

2013-09-01, 1392/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Aripiprazole versus risperidone in the treatment of children and adolescents with tic disorders, a double blind randomized controlled clinical trial

Public title

Aripiprazole versus risperidone in the treatment of children and adolescents with tic disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children and adolescents aged 6 to 18 years; total score of YGTS more than 21. Exclusion criteria: Marked general medical condition; hypersensitivity to the medications.

Age

From **5 years** old to **19 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Hafez Hospital

City

Shiraz

Postal code

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Approval date

2012-08-30, 1391/06/09

Ethics committee reference number

CT-91-3228

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

Tic disorder

ICD-10 code

F95

ICD-10 code description

Tic disorders

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

Yale global tic severity scale

Timepoint

Every 4 weeks

Method of measurement

interview

Secondary outcomes**1****Description**

Adverse effects checklist

Timepoint

every 4 weeks

Method of measurement

checklist

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

Risperidone up to 3 mg/day

Category

Treatment - Drugs

2**Description**

Aripiprazole up to 10 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**

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

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
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Web page address

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