

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Oct 2026

Twice-weekly aripiprazole for treating children and adolescents with tic disorder, a randomized controlled clinical trial

Protocol summary

Summary

This is an eight-week randomized controlled parallel group clinical trial to compare the efficacy of daily taking aripiprazole versus twice-weekly aripiprazole for treating 40 children and adolescents with tic disorder. Assessment using Yale global tic severity scale is used to measure tic severity at pre-intervention, and 4 and 8 weeks after starting the medication interventions.

Expected recruitment start date

2014-01-13, 1392/10/23

Expected recruitment end date

2014-09-14, 1393/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312263930N32**

Registration date: **2014-08-03, 1393/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-03, 1393/05/12

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

Scientific title

Twice-weekly aripiprazole for treating children and adolescents with tic disorder, a randomized controlled clinical trial

Public title

Twice-weekly aripiprazole for treating children and adolescents with tic disorder, a randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children and adolescents aged 5 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 **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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
Sciences**Street address**

Hafez Hospital

City

Shiraz

Postal code

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Approval date

2014-01-12, 1392/10/22

Ethics committee reference number

CT-92-6631

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**

tic severity

Timepoint

Every 4 weeks

Method of measurement

Yale global tic severity scale

Secondary outcomes

empty

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

aripiprazole up to 10 mg/day every day

Category

Treatment - Drugs

2**Description**

aripiprazole up to 10 mg/day every two times per week

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**Research Center for Psychiatry and Behavioral
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 addressVice-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 sourceVice 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

Name of organization / entity

Shiraz University of Medical sciences

Full name of responsible person

Ahmad Ghanizadeh

Position

Professor of Psychiatry

Other areas of specialty/work

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Person responsible for scientific 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