

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

An open - label study of Aripiprazole in the treatment of irritability in children with autistic disorder

Protocol summary

Summary

In this trial 5 children with autistic disorder who will be outpatients from psychiatric clinics after obtaining informed consent from caregivers will be recruited (the diagnosis of autism based on psychiatric interview and Autistic Diagnostic Interview - R). Patients will be treated with aripiprazole for 8 weeks. The dose of aripiprazole will be titrated up to 10 mg/day. Patients will be assessed at baseline and after 2, 4, 6 and 8 weeks. The measure of the outcome will be the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale and CGI-S. Side effects will be assessed with side effect checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209309645N2**
Registration date: **2012-10-29, 1391/08/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-29, 1391/08/08

Registrant information

Name

Nastaran Habibi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21334012209

Email address

na.habibi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An open - label study of Aripiprazole in the treatment of irritability in children with autistic disorder

Public title

Efficacy of aripiprazole in the treatment of autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: clinical diagnosis of autism; ages 3-6 years
Exclusion criteria: use of antidepressants or antipsychotics one week before trial (fluoxetine 1 month before trial); use of psychostimulants or benzodiazepines 72 hours before trial; severe medical diseases; current diagnosis of bipolar disorder, psychosis, schizophrenia, major depression

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 5

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Postal code

Approval date

2012-07-28, 1391/05/07

Ethics committee reference number

7299/801/91/ح

Health conditions studied

1

Description of health condition studied

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

severity of irritability

Timepoint

every two weeks

Method of measurement

The Aberrant Behavior Checklist (ABC)

Secondary outcomes

1

Description

extrapyramidal side effects

Timepoint

every two weeks

Method of measurement

Simpson-Angus Scale, the Barnes Akathisia Rating Scale, and the Abnormal Involuntary Movement Scale

2

Description

other side effects

Timepoint

every two weeks

Method of measurement

side effect checklist

3

Description

Clinical Global Impression-Improvement (CGI-I)

Timepoint

every two weeks

Method of measurement

Clinical Global Impression-Improvement (CGI-I)

Intervention groups

1

Description

aripiprazole 0.5 - 10 mg per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavn rehabilitation clinic

Full name of responsible person

Nastaran Habibi

Street address

Valiasr Avn., Monirieh Sq.

City

Tehran

2

Recruitment center

Name of recruitment center

Rofeydeh rehabilitation clinic

Full name of responsible person

Nastaran Habibi

Street address

Balooch St., Andarzgoo Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Nastaran Habibi

Street address

kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of Social Welfare and Rehabilitation 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

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Nastaran Habibi

Position

Child and adolescent psychiatrist/ assistant professor

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

Rastegar Blvd., Rey, Razi Psychiatric Hospital

City

Tehran

Postal code**Phone**

+98 21 3340 1220

Fax**Email**

dr_nhabibi@yahoo.com na.habibi@uswr.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Nastaran Habibi

Position

Child and adolescent psychiatrist/ assistant professor

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

Tehran

City

Tehran

Postal code**Phone**

+98 21 3340 1220

Fax**Email**

dr_nhabibi@yahoo.comna.habibi@uswr.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Nastaran Habibi

Position

Assistant professor/child and adolescent psychiatrist

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

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Postal code**Phone**

+98 21 2218 0083

Fax**Email**

na.habibi@uswr.ac.ir

Web page address

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