

# 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**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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*