

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Comparison of Aripiprazole versus Risperidone in Attention Disorder Hyperactivity Disorder in Children Under Six Years old age

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the safety and efficacy of Aripiprazole compare to Risperidone for the treatment of Attention Deficit Hyperactivity disorder in children under 6 years old.

Design: randomized, triple blind study, plus placebo

Settings and conduct: A child psychiatrist examines 40 children who are referred to child psychiatry clinic of Imam Hosein Hospital. They must fulfill criteria based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) for Attention Deficit Hyperactivity Disorder. **Participants:** They are 40 children from both gender and three to six years old age. The Inclusion Criteria are children from age three to age six with Attention Deficit Hyperactivity Disorder. They exclude from study if they have any other co morbidity that interferes with diagnosis and treatment like bipolar disorder; psychotic disorder; mental retardation; development delay disorders; Autistic disorder; and epilepsy. The other exclusion criteria are any medical condition, which preclude using medication or continuing medication. They do not have to take any psychotropic medication two weeks before starting the study. **Intervention:** Consent informant will be obtained from parents. Then children randomly divide into two groups. Group one takes Aripiprazole plus Risperidone placebo and the second group takes Risperidone plus Aripiprazole placebo. The clinician and parents are both blind to treatment. The starting dosage of Risperidone is 0.25 mg daily and it will increase every other week depends on the child response. The starting dosage of Aripiprazole is 1.25 mg daily and titrate upward biweekly based on clinical response. Follow-up measures are the ADHD Rating Scale (ADHD RS), Children-Global Assessment Scale (C-GAS), Conners Rating Scale-Parent (CRSP) and side effect questionnaire. They will assessed for three months at the baseline, week 2, week 4, week eight and week 12. Statistician calculates the results statistically at the end. **Main outcome:** decreasing

Attention Deficit Hyperactivity scores in ADHD Rating Scale (ADHD-RS), Children-Global Assessment Scale (C-GAS), Conners Rating Scale-Parent (CRSP) measures

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050413215N1**

Registration date: **2013-07-31, 1392/05/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-31, 1392/05/09

Registrant information

Name

Katayoon Razjouyan

Name of organization / entity

Behavioral Sciences Research Center, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-02-29, 1390/12/10

Expected recruitment end date

2013-05-31, 1392/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Aripiprazole versus Risperidone in Attention Disorder Hyperactivity Disorder in Children Under Six Years old age

Public title

The Comparison of Aripiprazole versus Risperidone in Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Children from age three to age six with Attention Deficit Hyperactivity Disorder Exclusion Criteria: co-morbidity with Bipolar Disorder; Psychotic Disorder; Mental Retardation; Autistic Disorder; Developmental Delay Disorder; Epilepsy; Any unstable physical conditions that preclude the use of oral medication or continuing treatment process; taking any psychotropic medication in two weeks prior to study.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

NA

Secondary trial Id

NA

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, Shahid Chamran Highway

City

Tehran

Postal code**Approval date**

2012-02-12, 1390/11/23

Ethics committee reference number

7812

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

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Hyperkinetic disorders

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

Attention Deficit Hyperactivity scores

Timepoint

two weeks, four weeks, eight weeks and twelve weeks after intervention

Method of measurement

ADHD-RS, C-GAS, CRSP

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

medication side effects

Timepoint

Second week. Four weeks, eight weeks, twelve weeks after the intervention.

Method of measurement

Side Effect Questionnaire

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

intervention group: The starting dosage of Aripiprazole is 1.25 mg daily and it will increase 1.25 mg per day every other week depends on the child response. At the same time, they will receive placebo of Risperidone that is similar to one mg tablet. The starting dosage of that is 1/4 of tablet per day. Placebo will titrate upward with 1/4

tablet each time the clinician increase the dosage of Aripiprazole.

Category

Placebo

2

Description

Control group: The starting dosage of Risperidone is 0.25 mg daily and it will increase 0.25 mg per day every other week depends on the child response. At the same time, they will receive placebo of Aripiprazole that is similar to five mg tablet. The starting dosage of that is 1/4 of tablet per day. Placebo will titrate upward with 1/4 tablet each time the clinician increase the dosage of Risperidone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person

Katayoon Razjouyan, Child and Adolescent Psychiatrist, Assistant Professor of Psychiatry

Street address

Shahid Madani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mohammad Rahmati Rodsari

Street address

Velenjak Str. , Shahid Chamran Highway

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Tehran

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, Shahid Beheshti 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

Behavioral Sciences Research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Arash Danesh

Position

Residency of Psychiatry

Other areas of specialty/work

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Other areas of specialty/work

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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