

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing response to risperidone and aripiprazol in preschool children with disruptive behavior disorders and ADHD: a randomized controlled trial

Protocol summary

Summary

Children with ADHD are frequently diagnosed and treated during elementary school. Atypical antipsychotic drugs have been studied in many disorders including ADHD and behavior disorders of children. Risperidone has been studied more than newer drugs; and studies about other drugs in this group is insufficient especially in preschool children. This study is performed with the aim of comparing safety and efficacy of two drugs, risperidone and aripiprazole in treatment of behavior disorders comorbid with ADHD in preschool children. Children attending child psychiatry clinic which have inclusion criteria in the case of parental acceptance and giving written consent are assigned to the study. They are randomly allocated to two groups and treated with risperidone or aripiprazole. Scores of Conners Rating Scale, parent form, and its subscales, CGI scores, body weight, and serum prolactin and FBS are measured at the beginning of treatment. Then parent Conners Scale scores and CGI score measurement and side effect assessment are performed in weeks 2, 4, and 8; and weight and laboratory measurements are repeated in week 8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041211983N2**
Registration date: **2014-06-29, 1393/04/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-29, 1393/04/08

Registrant information

Name

Parvin Safavi

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

safavip@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing response to risperidone and aripiprazol in preschool children with disruptive behavior disorders and ADHD: a randomized controlled trial

Public title

Comparing risperidone and aripiprazole in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 3 to 6 years; affected with disruptive behavior disorders and ADHD based on DSM-

IV criteria. Exclusion criteria : mental retardation or other developmental disorders such as autism; chronic physical or neurologic diseases; treatment with other psychotropic medications; development of severe and intolerable medication side effects .

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: **40**

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

Shahrekord University of Medical Sciences

Street address

Kashani street, Shahrekord University of Medical Sciences, Shahrekord

City

Shahrekord

Postal code

Approval date

2013-09-24, 1392/07/02

Ethics committee reference number

92-6-18

Health conditions studied

1

Description of health condition studied

ADHD

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

severity of ADHD and ODD symptoms

Timepoint

weeks 0, 2 , 4, and 8

Method of measurement

Short and Revised version of Conners Rating Scale parent form

2

Description

rate of improvement

Timepoint

weeks 2, 4 and 8

Method of measurement

CGI-I scale

Secondary outcomes

1

Description

drug side effects

Timepoint

weeks 2, 4 and 8

Method of measurement

checklist

2

Description

level of prolactine and fasting blood sugar

Timepoint

weeks 0 and 8

Method of measurement

lab data

3

Description

body weight

Timepoint

weeks 0 and 8

Method of measurement

weight measurement

Intervention groups

1

Description

In the first group oral risperidone with the dose of 0.25 mg once daily is started and and increased by 0.25 mg weekly up to 2 mg per day.

Category

Treatment - Drugs

2

Description

In the second group aripiprazole is started with the dose of 1.25 mg and increased by 1.25 mg weekly up to 10 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali clinic, Shahrekord University of Medical Sciences

Full name of responsible person

Dr Parvin Safavi

Street address

Shahrekord , Emam Ali clinic

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Mahmood Mobasheri

Street address

Shahrekord University of Medical Sciences, Kashani street, Shahrekord

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

Parvin Safavi

Position

child psychiatrist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Parvin Safavi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

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