Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Risperidon versus Haloperidol in the treatment of preschool children with attention deficit hyperactivity disorder

Protocol summary

Summary

Objective: The purpose of this study is to evaluate the safety and efficacy of Risperidone in comparison with Haloperidol for the treatment of Attention Deficit Hyperactivity Disorder in preschool children. Design: randomized, double blind study was designed: A child psychiatrist examines 46 children who are referred to child psychiatry clinic of Golestan hospital of Ahwaz. They must fullfill criteria based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision for Attention Deficit Hyperactivity Disorder. Participants:they are 46 children from both gender and three to six years old age. The inclusion criteria are Children from three to age six with Attention deficit hyperactivity disorder. They excludes from study if they have any other psychiatric comorbidity like mood disorder; anxiety disorder; psychotic disorder; mental retardation; tic and pervasive developemental disorder. They do not have to take any psychotropic medication two weeks before starting the study. Intervention: consent informant will be obtained from parents, the children randomly divided into two groups. Group one takes Haloperidol and the second one takes Risperidone. The clinician and parents are both blind to treatment. The starting dose of Risperidone is 0.25mg daily and it will increase every other week depending on clinical response and the maximum dose of Risperidone is 2 mg at the end of sixth week. Starting dose of Haloperidol is 0.5mg in two divided doses and will increase based on clinical response and tolerability and the maximum dose would be 0.075mg/kg. follow-up measures are the ADHD rating scale(ADHD-RS), Children Global Assessment Scale(C-GAS), Conners Rating Scale Parent(CRSP) and side effect questionarie. They will assess for 6 weeks at the baseline, 2 weeks, 4 weeks, 6 weeks after intervention. Statistician calculates the results statistically at the end.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082623766N1**
Registration date: **2015-09-14, 1394/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-14, 1394/06/23

Registrant information

Name
Leila Abdi
Name of organization / entity
Jondishapour University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 3374 3038
Email address
abdi.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

All financial fees of this study would be supported by vice Chancellor of Research Ahwaz Jondishapour Medical University of Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Risperidon versus Haloperidol in the treatment of preschool children with attention deficit hyperactivity disorder

Public title
Haloperidol and Risperidone efficacy for Attention Deficit Hyperactivity Disorder treatment

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: three to six years old children with attention deficit hyperactivity disorder; parent consent; ADHD rating scale greater than 20 and C-GAS lower than 50. exclusion criteria:any other medical or psychiatric comorbidity like mood disorder; anxiety disorder; mental retardation; psychotic disorder; tic; pervasive developemental disorder and taking any pharmacological or non pharmacological treatment in two weeks prior to study.

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: **46**

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
Ethics committee of Ahwaz Jondishapour University of Medical Sciences

Street address
Ethics Committee of Jondishapour University of Medical Sciences, university center, Golestan Boulevard

City
Ahwaz

Postal code

Approval date
2014-12-06, 1393/09/15

Ethics committee reference number
ajums.REC.13930305

Health conditions studied

1

Description of health condition studied
Attention deficit hyperactivity disorder

ICD-10 code
F90

ICD-10 code description
hyperkinetic disorder

Primary outcomes

1

Description
Attention deficit hyperactivity disorder score

Timepoint
baseline and 2 weeks, 4weeks, 6weeks after intervention

Method of measurement
Attention deficit hyperactivity disorder rating scale questionarie

2

Description
Children's Global Assessment

Timepoint
baseline and 6 weeks after intervention

Method of measurement
Children's Global Assessment Scale questionarie

3

Description
Attention deficit hyperactivity disorder score

Timepoint
baseline and 2 weeks, 4weeks, 6 weeks after intervention

Method of measurement
Conners Rating Scale-Parent version questionarie

Secondary outcomes

1

Description
Drug side effects

Timepoint
2 weeks, 4weeks, 6weeks after intervention

Method of measurement
Side effect questionaire

Intervention groups

1

Description
The second group took haloperidol orally with a starting dose of 0.5mg in two divided doses and it was increased depending on clinical response and tolerability. The maximum dose for haloperidol was 0.075mg/kg at the end of sixth week.

Category
Treatment - Drugs

2

Description
The first group took Risperidone tablet orally at the starting dose of 0.25mg and it was increased depending on clinical response and the maximum dose was 2mg at the end of sixth week.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
psychiatric clinic of child and adolescent of Golestan hospital

Full name of responsible person
Forough Riahi

Street address
psychiatry clinic, Golestan hospital, Golestan Boulevard

City
Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for research of Ahwaz Jondishapour University of Medical Sciences

Full name of responsible person
Feghi Mostafa

Street address
Vice chancellor for research of Ahwaz Jondishapour University of Medical Sciences, University center, Golestan Boulevard

City
Ahwaz

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 of Ahwaz Jondishapour 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
Ahwaz Jondishapour University of Medical Sciences

Full name of responsible person
Leila Abdi

Position
Resident of psychiatry

Other areas of specialty/work

Street address
Psychiatry department, Golestan hospital, Golestan Boulevard

City
Ahwaz

Postal code

Phone
+98 61 3391 7249

Fax

Email
Leilaabdi1635@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahwaz Jondishapour University of Medical Sciences

Full name of responsible person
Leila Abdi

Position
Resident of psychiatry

Other areas of specialty/work

Street address
Department of psychiatry, Golestan hospital, Golestan Boulevard

City
Ahwaz

Postal code

Phone
+98 61 3391 7249

Fax

Email
Leilaabdi1635@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahwaz Jondishapour University of Medical Sciences

Full name of responsible person

Leila Abdi

Position

Resident of psychiatry

Other areas of specialty/work

Street address

Department of psychiatry, Golestan hospital, Golestan Boulevard

City

Ahwaz

Postal code

Phone

+98 61 3391 7249

Fax

Email

leilaabdi1635@gmail.com

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