

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Risperidone and Aripiprazole as adjuvant Therapy in children with Attention deficit/hyperactivity disorder accompanied by oppositional defiant disorder treated by Methylphenidate.

Protocol summary

Study aim

The aim of current study is to compare the Risperidone and Aripiprazole as adjuvant therapy in children with Attention Deficit/hyperactivity disorder accompanied by oppositional defiant disorder treated by Methylphenidate through a double-blind, randomized, controlled trial.

Design

This study was conducted on 60 patients with ADHD with ODD in the range of 12-6 years old who were diagnosed by a child and adolescent psychiatrist which were eligible for inclusion in the study. Participants were randomly divided into two intervention groups and one control group and each participant was assigned a code. For 20 patients in group one, Ritalin and Risperidone tablets, and for 20 patients in the second group, Ritalin and Aripiprazole, and for the other 20 patients Ritalin and Placebo are given. Before starting the study, in the second, fourth and fourth weeks after the start of the study, the Parents' Conors Questionnaire and ADHDRating Scale were assessed and drug complications were assessed based on the Drug Complaint Questionnaire.

Settings and conduct

The research consisted of 60 patients with ADHD who referred to the Sanandaj Besat Hospital. Patients were randomly divided into intervention and control groups. One group receive methylphenidate and risperidone, and another group receive methylphenidate and aripiprazole, and control group receive the methylphenidate and placebo, The results of intervention at the beginning of the research and the second, fourth and eighth weeks are measured by the questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Diagnosis of ADHD and ODD based on DSM5 2-Age between 6 -12 years 3-without effective medication taking on mental status at least 2 weeks before the study. Exclusion criteria 1- Intellectual

disability based on clinical suspicious 2-presence of uncontrolled seizure 3-Drug sideeffects and hypersensitivity 4-Receiving of any other drug Diagnosis of ADHD and ODD based on DSM5 5-History of psychological disorder except ADHD and ODD 6-presence of medical diseases such as cardiac diseases

Intervention groups

The research consisted of 60 participants who were randomly divided in both intervention and control groups. Intervention group: A group of randomly selected patients received methylphenidate tablets (10 mg) for the first week (one quarter of the tablet at 8:00 am and one quarter of the tablet at 4:00 PM) and the second week (half the tablet at 8:00 am and half the tablet at 4:00 PM).) and from the third week afterwards (one tablet at 8:00 am and one tablet at 4:00 PM) Along with Risperidone powder for the first week (0.25 mg at 8:00 am and 0.25 mg at 8:00 pm) and the second week (0.5 mg at 8:00 am and 0.5 mg at 8:00 pm) and after the third week (one milligram at 8:00 am and one milligram at 8:00 pm). Intervention group: A group of randomly selected patients receive methylphenidate tablets (10 mg) for the first week (one quarter of the tablet at 8:00 am and one quarter of the tablet at 4:00 PM) and the second week (half the tablet at 8:00 am and half the tablet at 4:00 PM) and from the third week afterwards (one tablet at 8:00 am and one tablet at 4:00 PM) along with Aripiprazole for the first week (1.25 mg at 8:00 am and at 8:00 pm) and for the second week (2.5 mg at 8:00 am and at 8:00 pm) from the third week afterwards (5 mg at 8:00 am and at 8:00 pm). control group: this group receive methylphenidate tablets (10 mg) for the first week (one quarter of the tablet at 8:00 am and one quarter of the tablet at 4:00 PM) and the second week (half the tablet at 8:00 am and half the tablet at 4:00 PM) and from the third week afterwards (one tablet at 8:00 am and one tablet at 4:00 PM) along with placebo at 8:00 am and at 8:00 pm during 8 week of the study.

Main outcome variables

Treatment for ADHD and ODD patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160530028182N5**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

Registration date

2018-02-06, 1396/11/17

Registrant information

Name

Soleiman Mohammadzadeh

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3323 2168

Email address

dr.mohammadzadeh86@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-03, 1396/11/14

Expected recruitment end date

2018-04-18, 1397/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Risperidone and Aripiprazole as adjuvant Therapy in children with Attention deficit/hyperactivity disorder accompanied by oppositional defiant disorder treated by Methylphenidate.

Public title

Aripiprazole in ADHD and ODD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 6 -12 years Diagnosis of ADHD and ODD based on DSM5 without effective medication taking on mental status at least 2 weeks before the study

Exclusion criteria:

Intellectual disability based on clinical suspicious presence of uncontrolled seizure Drug side effects and hypersensitivity Receiving of any other drugs History of

psychological disorder except for ADHD and ODD presence of medical diseases such as cardiac diseases

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual based-simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug is prepared by the pharmacist and in coding packages which only the pharmacist is aware of its coding and delivered by researcher to the patient. Neither the investigator, nor the patient nor the analyst, knows the contents of the drug packages and the way they are coded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical University Of Kurdistan

Street address

pasdaran street Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2016-08-13, 1395/05/23

Ethics committee reference number

IR.MUK.REC.1395.135

Health conditions studied

1

Description of health condition studied

Attention deficit/hyperactivity disorder

ICD-10 code

F 90

ICD-10 code description

Attention-deficit hyperactivity disorders

2

Description of health condition studied

oppositional Defiant Disorder

ICD-10 code

F.91.3

ICD-10 code description

Primary outcomes

1

Description

Improvement in Attention-deficit symptoms

Timepoint

Baselin , second,fourth and eighth weeks after intervention

Method of measurement

Canner's and ADHD Rating scales

2

Description

Improvement in Impulsivity symptoms

Timepoint

Baselin , second,fourth and eighth weeks after intervention

Method of measurement

Canner's and ADHD Rating scales

3

Description

Improvement in hyperactivation symptoms

Timepoint

Baselin , second,fourth and eighth weeks after intervention

Method of measurement

Canner's and ADHD Rating scales

4

Description

Improvement in behavioral symptoms

Timepoint

Baselin , second,fourth and eighth weeks after intervention

Method of measurement

Canner's and ADHD Rating scales

Secondary outcomes

1

Description

severity of ADHD symptoms

Timepoint

Baselin , second ,fourth and eighth weeks after intervention

Method of measurement

ADHD Rating scale and CGI

2

Description

Drug Sideeffects

Timepoint

Baselin , second ,fourth and eighth weeks after intervention

Method of measurement

Sideeffects questionnaires

Intervention groups

1

Description

Intervention group: A group of randomly selected patients received methylphenidate tablets (10 mg) for the first week (one quarter of the tablet at 8:00 am and one quarter of the tablet at 4:00 PM) and the second week (half the tablet at 8:00 am and half the tablet at 4:00 PM).) and from the third week afterwards (one tablet at 8:00 am and one tablet at 4:00 PM) with a capsule containing Risperidone powder for the first week (0.25 mg at 8:00 am and 0.25 mg at 8:00 pm) and the second week (0.5 mg at 8:00 am and 0.5 mg at 8:00 pm) and after the third week (one milligram at 8:00 am and one milligram at 8:00 pm).

Category

Treatment - Drugs

2

Description

Intervention group: A group of randomly selected patients received methylphenidate tablets (10 mg) for the first week (one quarter of the tablet at 8:00 am and one quarter of the tablet at 4:00 PM) and the second week (half the tablet at 8:00 am and half the tablet at 4:00 PM).) and from the third week afterwards (one tablet at 8:00 am and one tablet at 4:00 PM) with a capsule containing Aripiprazole powder for the first week (1.25 mg at 8:00 am and 1.25 mg at 8:00 pm) and the second week (2.5 mg at 8:00 am and 2.5 mg at 8:00 pm) and after the third week (5 mg at 8:00 am and 5 mg at 8:00 pm).

Category

Treatment - Drugs

3

Description

Control group: A group of randomly selected patients received methylphenidate tablets (10 mg) for the first week (one quarter of the tablet at 8:00 am and one quarter of the tablet at 4:00 PM) and the second week (half the tablet at 8:00 am and half the tablet at 4:00 PM) and from the third week afterwards (one tablet at 8:00 am and one tablet at 4:00 PM) with a capsule containing placebo powder, one capsule at 8:00 am and one capsule at 8:00 pm during an 8-week period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical, Educational and Therapeutic Center of Besat Hospital

Full name of responsible person

Dr.Soleiman Mohammadzadeh

Street address

Medical, Educational and Therapeutic Center of Besat Hospital, Keshawarz Street

City

Sanandaj

Province

Kurdistan

Postal code

6619667761

Phone

+98 87 3328 2004

Email

dr.mohammadzadeh86@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

dr_ Farzin Rezaie

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pasdaran street

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Province

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66614713446

Phone

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Email

frrezaie@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr.Soleiman Mohammadzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Pasdaran street Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

66614713446

Phone

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Email

dr.mohammadzadeh86@muk.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr.Soleiman Mohammadzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

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Person responsible for updating data

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr.Soleiman Mohammadzadeh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Pasdaran street Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available