Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Risperidone and Aripiprazole as adjuvant Therapy in children with Atention deficit/hyperactivity disorder accopained 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 Atention Deficit/hyperactivity disorder accopained 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- Intelectual disability based on clinical suspicious 2-presence of uncontroled siezure 3-Drug sideeffects and hypersensivity 4-Recieving of any other drugDiagnosis of ADHD and ODD based on DSM5 5-History of psychological disorder except ADHD and ODD 6-presence of medical deasese such as cardiac deasese

Intervention groups

The research consisted of 60 participants who were randomly devided 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 seconed 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
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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 Atention deficit/hyperactivity disorder accopained by oppositional defiant disorder treated by Methylphenidate.

Public title
Aripiprazle 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:
Intelectual disability based on clinical suspicious presence of uncontroled siezure Drug side effects and hypersensivity Recieving of any other drugs History of psychological disorder except for ADHD and ODD presence of medical deasese such as cardiac deaseses
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 deliverd 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 Univercity Of Kurdestan
Street address
pasdaran street Sanandaj
City
Šanandaj
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
Improvment in Attention-deficit symptoms
Timepoint
Baselin , second,fourth and eighth weeks after intervention
Method of measurement
Canner's and ADHD Rating scales

2

Description
Improvment in Impulsivity symptoms
Timepoint
Baselin , second,fourth and eighth weeks after intervention
Method of measurement
Canner's and ADHD Rating scales

3

Description
Improvment in hyperactivation symptoms
Timepoint
Baselin , second,fourth and eighth weeks after intervention
Method of measurement
Canner's and ADHD Rating scales

4

Description
Improvment 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 quessionners

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 Terapeutic Center of Besat Hospital

Full name of responsible person
Dr.Soleiman Mohammadzadeh

Street address
Medical, Educational and Terapeutic 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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Sanandaj

Province
Kurdistan

Postal code
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

Street address
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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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66614713446

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+98 87 3366 4653

Email

dr.mohammadzadeh86@muk.ac.ir

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