Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of betahistine on hyperactivity disorder in children

Protocol summary

Study aim
The aim of this study was to evaluate the effect of betahistine on hyperactivity disorder in children.

Design
In this study, 76 patients with ADHD in the age range of 8-18 years old who are diagnosed with a child and adolescent psychiatrist are eligible to enter the study. Participants were randomly assigned to two intervention and control groups, and each participant was assigned a code. For 38 patients, one group received methylphenidate and betatisin tablets, and 38 patients received the second group of methylphenidate tablets and placebo.

Settings and conduct
The study included 76 patients with hyperactivity disorder who referred to the clinic of Besat Hospital in Sanandaj. The participants were randomly divided into two intervention groups. The first group received methylphenidate and betahistin and the methylphenidate and polassabs control group.

Participants/Inclusion and exclusion criteria
Having diagnostic criteria based on DSM-5 for ADHD with ODD; age 8 to 18 years; failure to use any effective psychological condition at least 2 weeks before the study. Exit conditions: Intellectual disability according to clinical suspicion; controlled seizure; complications and drug allergy.

Intervention groups
The research consisted of 76 participants who were randomly assigned to receive intervention and control group. Ritalin 10 mg for the first week of the week (one half a tablet at 8:00 and half a tablet at 14), from the second weekly 2 tablets (one morning) At 8 o'clock, one hour at 14 o'clock. The dose is 8 mg for the first week of the week, one tablet (half a tablet at 8 o'clock and half a tablet at 14 o'clock), and from the second week, 2 tablets (one morning at 8 o'clock, one o'clock 14 o'clock).

Main outcome variables
Treatment for ADHD patients side effects comparison

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160530028182N6**
Registration date: **2019-05-15, 1398/02/25**
Registration timing: **retrospective**

Last update: **2019-05-15, 1398/02/25**
Update count: **0**

Registration date
2019-05-15, 1398/02/25

Registrant information

Name
Soleiman Mohammadzadeh

Name of organization / entity
Kurdistan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of betahistine on hyperactivity disorder in children

Public title
Aripiprazle in ADHD and ODD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 8-18 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 diseases such as cardiac diseases
Age
From **8 years** old to **18 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: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Individual based-simple randomization
Blinding (investigator's opinion)
Triple 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
Kurdestan University of Medical Sciences
Street address
Pasdaran street Sanandaj
City
Śanandaj
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
F90
ICD-10 code description
Attention deficit/hyperactivity disorder

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

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

Intervention groups

1

Description
Intervention group: the research consisted of 76 participants who were randomly assigned to receive intervention and control group. Ritalin 10 mg for the first week of the week (one half a tablet at 8:00 and half a tablet at 14), from the second weekly 2 tablets (one morning) At 8 o'clock, one o'clock 14) and in the case of

a weight of over 30 kilograms, from the second week, 3 tablets (one and a half hours at 8 o'clock, one and half hours at 14 o'clock) are prescribed daily. The dosage is 8 mg per day for the first week of the week (half a tablet at 8:00 and half a tablet at 14) and from the second week, 2 tablets (one morning at 8, one hour at 14)

Category

Treatment - Drugs

2

Description

Control group: Ritalin 10 mg for the first week of the week (one half a tablet at 8:00 and half a tablet at 14), from the second weekly 2 tablets (one morning) At 8 o'clock, one o'clock 14) and in the case of a weight of over 30 kilograms, from the second week, 3 tablets (one and a half hours at 8 o'clock, one and half hours at 14 o'clock) are prescribed daily. herapeutic dosage of placebo is prescribed a tablet daily for the first week (one cap in the morning at 8 o'clock) and 2 cap are daily prescribed in the second week (one cap in the morning at 8 o'clock, one cap at 16 o'clock).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical, Educational and Terapeutic Center of Besat Hospital

Full name of responsible person

Soleiman Mohammadzadeh

Street address

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

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Web page address

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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Grant name

Grant code / Reference number

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

No

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

Soleiman Mohammadzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr.Soleiman Mohammadzadeh

Position
Associate professor

Latest degree
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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