Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison Methylphenidate and Buspirone as Adjuant therapy in children with ADHD treated by Methylphenidate mono therapy

Protocol summary

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

Design
study was conducted on 50 patients with ADHD 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 control group and each participant was assigned a code. For 25 patients in group one, Ritalin and Buspirone tablets, and for 25 patients in the second group, Ritalin and Placebo are given.

Settings and conduct
The research consisted of 50 patients with ADHD who referred to the Sanandaj Besat Hospital. Patients were randomly divided into two intervention groups and control group. 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:Diagnosis of ADHD based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5),Age between 6 -12 years Exclusion criteria:1-Intellectual disability based on clinical suspicious 2-presence of uncontrolled seizure

Intervention 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 Buspirone powder 5 milligram 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 afterwards the third week (five milligram at 8:00 am and five milligram at 4:00 pm).

Main outcome variables
Treatment for ADHD patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160530028182N7**
Registration date: **2019-11-03, 1398/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-03, 1398/08/12**
Update count: **0**

Registration date
2019-11-03, 1398/08/12

Registrant information

Name
Soleiman Mohammadzadeh

Name of organization / entity
Kurdistan University of Medical Sciences

Country
Iran (Islamic Republic of)

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dr.mohammadzadeh86@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Methylphenidate and Buspirone as Adjuant therapy in children with ADHD treated by Methylphenidate mono therapy

Public title

Effect of Buspirone in ADHD

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

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

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

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran street

City

Šanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2017-07-24, 1396/05/02

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 disorders

Primary outcomes

1

Description

Clinical Profile of illness reported by parents

Timepoint

Baselin , second,fourth and eighth weeks after intervention

Method of measurement

Canner's and ADHD Rating scales

2

Description

symptoms severity reported by parents

Timepoint

Baselin , second ,fourth and eighth weeks after intervention

Method of measurement

ADHD Rating scale and CGI

3

Description

efficacy of treatment

Timepoint

Baselin , second ,fourth and eighth weeks after intervention

Method of measurement

The Clinical Global Impressions (CGI) Scale used to rate the symptoms change over time, and efficacy of medication, taking into account the patient's clinical condition by clinicians.

Secondary outcomes

1

Description
Drug side effects
Timepoint
Second, fourth and eighth weeks after intervention
Method of measurement
checklist by clinical interview and exam

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 Buspirone powder 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 andhalf the tablet at 4:00 pm) and after the third week (one tablet at 8:00 am and one tablet at 4:00 pm).
Category
Treatment - Drugs

2

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 for the first week (1.25 mg at 8:00 am and 1.25 mg at 4:00 pm) and the second week (2.5 mg at 8:00 am and 2.5 mg at 4:00 pm) and after the third week (5 mg at 8:00 am and 5 mg at 4:00 pm).
Category
Treatment - Drugs

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
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Postal code
6619667761
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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
Street address
Pasdaran street
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Sanandaj
Province
Kurdistan
Postal code
66614713446
Phone
+98 87 3366 4653
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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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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

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Psychiatrics

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Web page address

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