

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison Methylphenidate and Bupirone 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 Bupirone 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 Bupirone 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 Bupirone 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)

##### Phone

+98 87 3323 2168

##### Email address

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 Adjuvant 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:**  
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**  
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 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**

Ethics committee of Kurdistan University of Medical Sciences

**Street address**

Pasdaran street

**City**

Sanandaj

**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**

Baseline , second, fourth and eighth weeks after intervention

**Method of measurement**

Canner's and ADHD Rating scales

### 2

**Description**

symptoms severity reported by parents

**Timepoint**

Baseline , second ,fourth and eighth weeks after intervention

**Method of measurement**

ADHD Rating scale and CGI

### 3

**Description**

efficacy of treatment

**Timepoint**

Baseline , 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 and half 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 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

##### Street address

Pasdaran street

##### City

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

**Street address**

Pasdaran street Sanandaj

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Sanandaj

**Province**

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66614713446

**Phone**

+98 87 3366 4653

**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

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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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**Email**

dr.mohammadzadeh86@muk.ac.ir

**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