

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Buspirone versus Methylphenidate in the treatment of Attention Deficit Hyperactivity Disorder: a double-blind and randomized trial

Protocol summary

Summary

Objective: The efficacy and side effects of buspirone in treatment of children with attention-deficit/hyperactivity disorder (ADHD) compared with methylphenidate (MPH). Method: A total of 34 children with ADHD as defined by DSM-IV-TR were randomized to buspirone (0.5 mg/kg/day) or methylphenidate (0.3-1 mg/kg/day) for a 6-week. The principle measures of outcome were the teacher and parent ADHD Rating Scale. Side effects were assessed by special side effect checklist of each drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901292000N3**
Registration date: **2010-05-01, 1389/02/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-01, 1389/02/11

Registrant information

Name

Rozita Davari Ashtiani

Name of organization / entity

Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 1023

Email address

rodavari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Behavioral Sciences Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2007-02-20, 1385/12/01

Expected recruitment end date

2008-06-04, 1387/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Buspirone versus Methylphenidate in the treatment of Attention Deficit Hyperactivity Disorder: a double-blind and randomized trial

Public title

Buspirone in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ADHD diagnosis according to DSM-VI criteria that scored above 20 in ADHD-Rating Scale. Exclusion criteria: evidence of a mental retardation or a major psychiatric problem other than oppositional defiant disorder and conduct disorder or receiving any psychotropic medication through 2 weeks before initiating treatment; medical disorders that would preclude the safe use of methylphenidate or buspirone.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 34

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Behavioral Sciences and Research Center of Shahid Beheshti University of Medical Sciences

Street address

Imam Hossein Hospital, Shahid Madani st

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

87-01-102-5964

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

hyperactivity, impulsivity and inattention symptoms according to parent and teacher point of view

Timepoint

baseline, 2, 4 and 6 weeks after the medications started.

Method of measurement

ADHD Rating Scale,(parent and teacher form)

Secondary outcomes

1

Description

side effects

Timepoint

every 2 weeks

Method of measurement

check list

Intervention groups

1

Description

Intervention 1: buspirone was initiated with 0/5 mg/kg/day to maximum 45mg/day

Category

Treatment - Drugs

2

Description

Intervention 2: Methylphenidate was initiated with 0/5 mg/kg/day and adjusted to maximum 60 mg per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Child and adolescent psychiatric outpatient clinic of Imam-Hossein hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behavioral Sciences and Research Center of Shahid Beheshti University of Medical Sciences.

Full name of responsible person

Dr Alireza Zahiroddin

Street address

Imam Hossein Hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Behavioral Sciences and Research Center of Shahid Beheshti University of Medical Sciences.

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rozita Davari Ashtiani

Position

MD, assistant professor

Other areas of specialty/work**Street address**

Imam Hossein Hospital, Shahid Madani street

City

Tehran

Postal code**Phone**

+98 21 7755 1023

Fax**Email**

rodavari@sbmu.ac.ir

Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*