Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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