

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Buspirone versus Methylphenidate in 6-16 aged children with Attention Deficit/Hyperactive Disorder(ADHD). A crossover study

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 40 children aged 6-16 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 8-week in a crossover study. 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: **IRCT201104116168N1**
Registration date: **2011-06-12, 1390/03/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-12, 1390/03/22

Registrant information

Name

Mahin Eslami Shahrabaki

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Neuroscience Research Center Kerman University of Medical Sciences

Expected recruitment start date

2010-09-11, 1389/06/20

Expected recruitment end date

2011-03-11, 1389/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Buspirone versus Methylphenidate in 6-16 aged children with Attention Deficit/Hyperactive Disorder(ADHD). A crossover study

Public title

Buspirone in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ADHD diagnosis according to DSM-IV-TR criteria that scored above 20 in ADHD-Rating Scale. Exclusion criteria: evidence of a mental retardation(IQ<70) 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 **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Neuroscience Research Center of Kerman University of Medical Sciences, Kerman-Iran

Street address

Opposit of Besat Clinic, Ebn-e-sina Street , Jahad Blv, Kerman, Iran

City

Kerman

Postal code

7619813159

Approval date

2011-03-16, 1389/12/25

Ethics committee reference number

48-89

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

every 2 weeks

Method of measurement

ADHD Rating Scale (parent and teacher form)

Secondary outcomes

1

Description

side effects include increase or decrease of appetite, weight and sleep, tic, stomachach

Timepoint

every 2 weeks

Method of measurement

Checklist of each drug side effects

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 0/5-1 mg/kg/day and adjusted to maximum 60 mg per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital , Jomhori Blvd, Kerman, IRAN and Besaat Clinic , Ebn-e- Sina Street Jahad Blv

Full name of responsible person

Dr Mahin Eslami Shahrbabki

Street address

Shahid Beheshti Hospital , Jomhori Blv, Kerman ,Iran

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neuroscience Research Center Kerman University of Medical Sciences, Kerman ,Iran

Full name of responsible person

Dr. Vahid Sheibani

Street address

Opposit of Besaat Clinic , Ebn -e-sina street, Jahad Blv, Kerman, Iran

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Grant name

124704

Grant code / Reference number

10506

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

Yes

Title of funding source

Neuroscience Research Center Kerman University of Medical Sciences, Kerman ,Iran

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

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Mahin Eslami Sharbabaki

Position

MD,assistant professor

Other areas of specialty/work

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Position

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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