Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Shahrbabki
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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
0pposit 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

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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

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Full name of responsible person

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Position

MD,assistant professor

Other areas of specialty/work

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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