

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Double-blind randomized comparison of efficacy and side effects of Bupropion versus methyl phenidate in children with Attention Deficit Hyperactivity Disorder (ADHD)

Protocol summary

Summary

The overall goals: Comparison of efficacy and side effects of Bupropion versus Methylphenidate in Children with Attention Deficit Hyperactivity Disorder (ADHD). Study design: Double-Blind. Inclusion criteria: 1- Children 6 to 12 years old Diagnosed With ADHD based on DSM-IV-TR; 2- Not having Medical Problems Including a history of Epilepsy; 3- Not having the history of taking Bupropion or Methylphenidate; 4- not taking other psychiatric drugs. Exclusion criteria: 1- Not wanting parents to complete research Projects; 2- Having serious complications such as epilepsy. Sample size: 40. Methods of execution and interventions: 40 Children with ADHD (Referred to Ibne-sina child psychiatrist clinic) who have the inclusion criteria are selected through available consecutive sampling and will be assigned randomly to treatment with Methylphenidate and Bupropion. Children will be assessed with ADHD-RS (Teacher and Parent) and C-GAS, at Baseline then after 4 and 8 weeks of treatment. Dosing range is 0.3 to 0.8 mg/kg for Methylphenidate and 3-6 mg/kg for Bupropion. Primary outcomes: 1- ADHD-RS. 2- C-GAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012295500N1**
Registration date: **2012-03-29, 1391/01/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-29, 1391/01/10

Registrant information

Name

Mohsen Pasandideh

Name of organization / entity

Ibn-e-sina hospital, Mashad university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Research vice chancellor of Mashad university of medical sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-06-21, 1390/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind randomized comparison of efficacy and side effects of Bupropion versus methyl phenidate in children with Attention Deficit Hyperactivity Disorder (ADHD)

Public title

Comparison of effect of methyl phenidate (Ritalin) and bupropion in children with hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Children 6 to 12 years old with diagnosis of ADHD on the basis of DSM-IV-TR; 2-children without MR (IQ>70); 3-children without medical and neurologic problems specially with a history of epilepsy; 4-children without eating disorders (because of being prone to seizure due to bupropion); 5-agreement of parents in research participation; 6-the child that does not have the history of using Methyl phenidate and Bupropion and other psychiatric drugs. Exclusion criteria: 1-disagreement of parents during the research; 2-existence of severe side effects like neurologic disorders such as convulsion in curing groups.

Age

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

Gender

Both

Phase

3

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

Ethics committee of Mashad university of medical sciences

Street address

Central departement of Mashad university of medical sciences, Daneshgah street

City

Mashad

Postal code

91388-13944

Approval date

2009-12-15, 1388/09/24

Ethics committee reference number

6543

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Assessment of children (C-GAS)

Timepoint

Before intervention, the fourth week and eighth week after the start of intervention

Method of measurement

Teacher and parent questionnaire

2

Description

Attention Deficit, hyperactivity Disorder Scale

Timepoint

Before intervention, the fourth week and eighth week after the start of intervention

Method of measurement

Teacher and parent questionnaire

Secondary outcomes

1

Description

Side effects of bupropion

Timepoint

the fourth week and eighth week after the start of intervention

Method of measurement

Questionnaire check list

2

Description

Side effects of stimulant drugs

Timepoint

the fourth week and eighth week after the start of intervention

Method of measurement

Questionnaire check list

Intervention groups

1

Description

Bupropion, 75 milligram tablets, orally, two times a day, Morning and afternoon

Category

Treatment - Drugs

2

Description

Methylphenidate (Ritalin) tablets, 10 mg, orally, two times a day, morning and evening, based on weight 0.3-0.8 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic of Ebn-e-Sina Psychiatry Hospital

Full name of responsible person

Atefeh Soltanifar, MD, Subspecialist of childs and adolescents psychiatry

Street address

Ibn-e-Sina Hospital, Horeameli Avenue

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Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice chancellor of Mashad university of medical sciences

Full name of responsible person

Mrs. Ardekanian

Street address

Research vice chancellor, Ghoreshi departement, Danshgah street

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research vice chancellor of Mashad 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

Name of organization / entity

Mashad university of medical sciences

Full name of responsible person

Mohsen Pasandideh

Position

Intern

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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