Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

Iran (Islamic Republic of)

Phone

+98 57 1226 5016

Email address

pasandidem821@mums.ac.ir

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-existance 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
City
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
City
Mashad
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
Other areas of specialty/work
Street address
Ibn-e-Sina Hospital, Horeameli Avenue
City
Mashad
Postal code
Phone
+98 51171127019
Fax
+98 51 1711 2545
Email
pasandidem821@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashad university of medical sciences
Full name of responsible person
Dr. Atefeh Soltanifar
Position
Subspecialist of childs and adolescents psychiatry
Other areas of specialty/work
Street address
Ibn-e-Sina Hospital, Horeameli Avenue
City
Mashad
Postal code
8313491959
Phone
+98 51 1712 4184
Fax
+98 51 1712 4184
Email
Ebnesina.hos@mums.ac.ir , soltanifara@mums.ac.ir
Web page address
http://www.mums.ac.ir/sina/fa/index

Person responsible for updating data

Contact
Name of organization / entity
Mashad university of medical sciences
Full name of responsible person
Mohsen pasandideh
Position
Intern
Other areas of specialty/work
Street address
Ibn-e-Sina Hospital, Horeameli Avenue
City
Mashad
Postal code
Phone

+98 51171127019
Fax
+98 51 1711 2545
Email
pasandidem821@mums.ac.ir ,
Ebnesina.hos@mums.ac.ir
Web page address
http://www.mums.ac.ir/sina/fa/index

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