

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of therapeutic effect of bupropion and venlafaxine in children with Attention deficit hyperactivity disorder

Protocol summary

Summary

Objectives: The gold standard for the main symptoms of children with attention deficit hyperactivity disorder (ADHD) is stimulants. But some patients have not got the suitable therapy due to the drug side effect or not responding. So other anti-depression medicines including bupropion and venlafaxine could be help. The aim of present study is to evaluate the therapeutic effect of bupropion and venlafaxine in children with ADHD.

Method: In this study, 40 children between 7 to 10 years old with ADHD according to the ADHD rating scale IV and psychiatric interview and side effect or not responding to Ritalin are entered to the study. These children are randomly divided into two similar groups' respects to age, gender and education. **Intervention:** First group: The patients will be received ritalin with previous dose beside venlafaxine 0.5 mg to Kg weight during the first week. In the second week, half of the first week ritalin dose beside venlafaxine will be given. Venlafaxine dose of 0.1 mg per kg body weight per week is increased till reach to 1.4 mg per kg body weight in the tenth week. Ritalin is deleted from the third week onwards. For the second group: In the first week of 1.4 mg per kg body weight bupropion (beside previous dose ritalin) is given. In the second week, half of the Ritalin dosage beside 1.91 mg per kg body weight bupropion is given. From the second week, 0.51 mg per kg body weight of bupropion is added every week till received to 6 mg per kg of body weight. Ritalin is deleted from the third week onwards. The main outcomes: Response to treatment in both groups will be evaluated by Connors Parent Questionnaire, ADHD rating scale IV and Clinical Global Impression Scale before the study, after each two weeks and after completing the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306189175N5**

Registration date: **2013-07-12, 1392/04/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-12, 1392/04/21

Registrant information

Name

Lida Jarahi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 1882 9262

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jarahil@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2011-12-19, 1390/09/28

Expected recruitment end date

2013-10-20, 1392/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of bupropion and venlafaxine in children with Attention deficit

hyperactivity disorder

Public title

Comparison of effect of bupropion and venlafaxine in children with hyperactivity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children with attention deficit hyperactivity disorder between 7 to 10 years old with IQ more than 70 by Rion quiz and have not any psychiatric and neurological problem at interview. Exclusion criteria: Children with attention deficit hyperactivity disorder lower than 7 years old and more than 10 years old, IQ lower than 70 and any psychiatric and neurological problem at interview.

Age

From **7 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2011-04-06, 1390/01/17

Ethics committee reference number

511/71

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90.0, F90

ICD-10 code description

Attention deficit: disorder with hyperactivity, hyperactivity disorder and syndrome with hyperactivity

Primary outcomes

1

Description

Percentage of response to treatment

Timepoint

before the study, after each two weeks and after completing the study

Method of measurement

Connors Parent Questionnaire

2

Description

Percentage of response to treatment

Timepoint

before the study, after each two weeks and after completing the study

Method of measurement

Clinical Global Impression Scale

3

Description

Percentage of response to treatment

Timepoint

before the study, after each two weeks and after completing the study

Method of measurement

Attention deficit hyperactivity disorder rating scale IV

Secondary outcomes

empty

Intervention groups

1

Description

First group: The patients will be received ritalin with previous dose beside venlafaxine 0.5 mg to Kg weight during the first week. In the second week, half of the first week ritalin dose beside venlafaxine will be given. Venlafaxine dose of 0.1 mg per kg body weight per week is increased till reach to 1.4 mg per kg body weight in the tenth week. Ritalin is deleted from the third week onwards.

Category

2**Description**

For the second group: In the first week of 1.4 mg per kg body weight bupropion (beside previous dose ritalin) is given. In the second week, half of the Ritalin dosage beside 1.91 mg per kg body weight bupropion is given. From the second week, 0.51 mg per kg body weight of bupropion is added every week till received to 6 mg per kg of body weight. Ritalin is deleted from the third week onwards.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ibn Sina Hospital

Full name of responsible person

Dr Peiman Hashemian

Street address

Ibn Sina Hospital, Hor Amerli Street

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Peiman Hashemian

Position

Child and Adolescent Psychiatrist

Other areas of specialty/work**Street address**

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Position

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Web page address

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