Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 stimulators. 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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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 Mashad 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

Treatment - Drugs

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

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue, boo Ali square

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Web page address

Person responsible for scientific 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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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Peiman Hashemian

Position

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Other areas of specialty/work

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avenue,boo Ali square
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+98 51 1888 2926
Fax
Email
hashemianp@mums.ac.ir
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