Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of neurofeedback versus methylphenidate in the treatment of children with Attention Deficit Hyperactivity Disorder

Protocol summary

Summary

Type of study: Randomized clinical trial. Aim: to determine the effectiveness of neurofeedback versus methylphenidate in the treatment of children with Attention Deficit Hyperactivity Disorder. Inclusion criteria: 1-Diagnosis of ADHD based on DSM-IV criteria by child and adolescent psychiatrists; 2- age of 7- 18 years; 3- IQ above 85 based on WISC-III-R. Exclusion criteria:1- major learning problems; 2- request of parent to exit from the study; 3- use of antipsychotic drugs in the month before the initiation of the study. 4- history of neurofeedback intervention at least for 10 sessions. Types of interventions:1) neurofeedback; 2)medication 3)medication +neurofeedback. The participants will be recruited from 4 child psychiatry clinics. Then they will be refered to the main clinic which all the intervention will be conducted there. Methylphenidate dose will be adjusted based on optimal dose by a child and adolescent psychiatrist whom visits all the patients. They will be assessed 1 week before the start and each month through the study ,the last assessment will be on a week after the completion of the research. The main outcome measures are: conners, TOVA. The rater will be blind to the groups of patients. The duration of the treatment is 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804132000N2**
Registration date: **2013-02-15, 1391/11/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-02-15, 1391/11/27

Registrant information

Name
Rozita Davari Ashtiani
Name of organization / entity
Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 7755 1023
Email address
rodavari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Behavioral sciences research center, Shahid beheshti university of medical sciences

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of neurofeedback versus methylphenidate in the treatment of children with Attention Deficit Hyperactivity Disorder

Public title

Neurofeedback in the treatment of Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Diagnosis of ADHD based on DSM-IV-

TR criteria by child and adolescent psychiatrists; 2- age of 7- 18 years; 3- IQ above 85 based on WISC-III-R; 4- parent consent for the participation in the study. Exclusion criteria: 1- neurological disorders; 2- major learning problems; 3- request of parent to exit from the study; 4- use of antipsychotic drugs in the month before the initiation of the study; 5- history of neurofeedback intervention at least for 10 sessions.

Age
From **7 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Behavioral sciences Research Center, Shahid Beheshti University of Medical sciences

Street address
Shahid Madani Street, Imam Hossein Hospital, Behavioral Sciences Research center

City
Tehran

Postal code
1617763141

Approval date
2012-12-23, 1391/10/03

Ethics committee reference number
1391-1-91-9876

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
ADHD symptoms

Timepoint
1 week before the initiation and each monththrough the study and 1 week after the end of the intervention

Method of measurement
conners ADHD rating scale

Secondary outcomes

1

Description
attention

Timepoint
1 week before , and 1 week after the end of the trial

Method of measurement
Test of Variables of Attention

Intervention groups

1

Description
Group 1:treatment with methylphenidate started with 5mg BD and the dose will adjust in 2 weeks according to response and side effects by a child psychiatrist

Category
Treatment - Drugs

2

Description
Group 3:treatment with the combination of methylphenidate and neurofeedback. Both of these interventions is implemented in the same instruction as in group 1 and 2

Category
Other

3

Description
Group 2: treatment with neurofeedback 2 times a week by an expert in a special clinic.In this method , we are going to increase beta waves in the brain and as a result increasing attention

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Rozita Davari Ashtiani Clinic
Full name of responsible person
Rozita Davari Ashtiani
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Dr Elham Shirazi Clinic
Full name of responsible person
Elham Shirazi
Street address
City
Tehran

3

Recruitment center
Name of recruitment center
Dr Javad Alaghband Rad Clinic
Full name of responsible person
Javad Alaghband Rad
Street address
City
Tehran

4

Recruitment center
Name of recruitment center
Dr Nasrin Amiri Clinic
Full name of responsible person
Nasrin Amiri
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Behavioral Sciences Research center, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Alireza Zahiroddin
Street address
Imam Hossein Hospital , Shahid Madani Street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Behavioral Sciences Research center, Shahid Beheshti 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Javad Alaghband Rad
Position
Associate Professor , Child & Adolescent Psychiatrist
Other areas of specialty/work
Street address
Roozbeh Hospital, South Kargar Street
City
Tehran
Postal code
Phone
+98 21 5541 9151
Fax
Email
alaghbandrad@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of medical Sciences
Full name of responsible person
Dr Javad Alaghband rad
Position
MD, Child & Adolescent psychiatrist
Other areas of specialty/work
Street address
Roozbeh Hospital, South Kargar Street:
City
Tehran
Postal code
Phone
+98 21 5541 9151
Fax
Email
alaghbandrad@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Rozita davari Ashtiani

Position
Associate Professor, child & Adolescent Psychiatrist

Other areas of specialty/work

Street address
Imam Hossein Hospital, Shahid Madani Street

City
Tehran

Postal code

Phone
+98 21 7755 1023

Fax

Email

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