Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of transcranial direct electrical stimulation cognitive functions in children with attention deficit hyperactivity disorder

Protocol summary

Study aim
Determining the effect of transcranial direct electrical stimulation on cognitive function in children with attention deficit hyperactivity disorder

Design
Clinical trial with control group with two groups only without blinding randomized on 37 patients. Randomized by a table of random numbers

Settings and conduct
This study will be conducted as a clinical trial in 22 Bahman clinic in 2023. Each of the members of the two groups will be individually pre-tested using the Swanson-Nolan and Pelham questionnaire, the audio-visual continuous assessment software (IVA-2).The method of applying stimulation in tDCS will be in such a way that the sponge pad, which is actually the covering of the electrodes, will be soaked with 3% sodium chloride and the electrodes will be placed inside it. Anode tDCS stimulation with an intensity of 2 mA for 21 minutes and in ten sessions will be performed on the experimental group. One group received standard treatment and the other group received tdcs in addition to standard treatment, and the post-test will be performed on all participants.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Children under 12 years old 3- Willingness to study Conditions of non-entry of participants: 1- Unwillingness to participate in the study 2-Suffering from another psychiatric disorder 3- The presence of metal parts in the body 4- Seizure history

Intervention groups
This study will be conducted as a clinical trial on children with attention deficit hyperactivity disorder. One group will receive the standard treatment and one group will receive the tdcs method in addition to the standard treatment

Main outcome variables
Short term memory; Visual and spatial skills; Executive functions; Attention and concentration; Language; Awareness of time and place; Direct electrical stimulation

General information

Reason for update
Changing the sample size.

Acronym

IRCT registration information
IRCT registration number: **IRCT20231030059908N1**
Registration date: **2023-11-21, 1402/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-22, 1403/12/04**
Update count: **1**

Registration date
2023-11-21, 1402/08/30

Registrant information

Name
Fateme Mollazade

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5523 4944

Email address
f.mollazade1159@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-01, 1402/09/10

Expected recruitment end date
2024-05-30, 1403/03/10

Actual recruitment start date
2023-09-23, 1402/07/01
Actual recruitment end date
2025-01-18, 1403/10/29
Trial completion date
2025-01-18, 1403/10/29

Scientific title
Investigating the effectiveness of transcranial direct electrical stimulation cognitive functions in children with attention deficit hyperactivity disorder

Public title
Investigation the Effect of transcranial Direct Current Stimulation (TDCS) in attention-deficit, hyperactivity disorder (ADHD)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ADHD
Exclusion criteria:
Unwilling to participate in the study Having another psychiatric disorder The presence of metal grafts in the body History of seizures
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Actual sample size reached: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is using a table of random numbers that are selected through a random number computer.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad Azad University of Medical Sciences
Street address
No14, Emam khomeini Ave, Mashhad Town.
City
Mashhad
Province
Razavi Khorasan
Postal code
9187147578
Approval date
2023-07-19, 1402/04/28
Ethics committee reference number
IR.IAU.MSHD.REC.1402.045

Health conditions studied

1

Description of health condition studied
ADHD
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The score of Swanson-Nolan and Pelham questionnaire (SNAP_4)
Timepoint
The beginning of the study 30 days after the start of the study
Method of measurement
Swanson-Nolan and Pelham questionnaire

2

Description
Cognitive assessment
Timepoint
The first day before the start, the tenth day.
Method of measurement
IVA-2 cognitive assessment software

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving transcranial direct stimulation for 21 minutes in 10 sessions
Category
Treatment - Devices

2

Description

Intervention group: In addition to the standard treatment, the new treatment receives transcranial direct electrical stimulation

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

22Bahman hospital clinic.

Full name of responsible person

Mansoure Mirzadeh

Street address

Kuhsangi complex, No8, Alale Ave, pirouzi2/1 Blv. Mashhad town

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798666

Phone

+98 51 5523 4944

Email

f.mollazade1159@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Touraj Zandbaf

Street address

No.14 , Emam khomein Ave., Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798666

Phone

+98 51 3225 0041

Email

IMRC@mshdiau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fateme Mollazade

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Psychiatrics

Street address

No. 8, Alale Ave, Pirozi Blv, Mashhad town.

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798666

Phone

005155234944

Email

F.mollazade1159@GMAIL.COM

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mansoure Mirzade

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

No. 8, Aref street, Mashhad town.

City

Mashhad

Province

Razavi Khorasan

Postal code

9176982756

Phone

+98 51 3848 9800

Email

mirzadeh.mansoureh@gmail.com

Person responsible for updating data

f.mollazade1159@gmail.com

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fateme Mollazade

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Psychiatrics

Street address
No.8, Alaleh Ave, Pirouzi Blvd, Mashhad Town

City
Mashhad

Province
Razavi Khorasan

Postal code
9193798666

Phone
+98 51 5523 4944

Fax

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available