Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effect of combining tDCS and behavioral intervention on behavioral problems in children with autism spectrum disorder

Protocol summary

Summary

(1) Main aim: Effect of combining tDCS and behavioral intervention on behavioral problems in children with autism spectrum disorder, Goals: A- Comparison between the combining tDCS and PRT with placebo tDCS and PRT group on behavioral problems in 10 up to 16-year-old-children with autism spectrum disorder. (2) Design: This study is a randomized single blind clinical controlled trial. (3) Setting and conduct: Study population consisted of children with autism spectrum disorder are referred to clinical centers of Hamadan university of medical sciences that 30 person divided in 2 groups included tDCS with Pivotal response treatment(PRT), placebo tDCS and PRT will be randomly selected. Inclusion criteria: Diagnosis of autism spectrum disorder based on the psychiatrist's interview or neuropediatrist According to DSM-5 criteria and using Gilliam autism rating scale(GARS). Be at least 10 and up to 16 years, weigh at least 5 Kg, Mental age be at least 18 months. Exclusion criteria: The people with acute and serious mental disorders such as schizophrenia, etc, People with other medical illnesses such as head injuries, Neurologic Diseases, A history of seizure, auditory and visual deficit. Intervention and time: Phase 1- In this phase all patients will receive PRT for 8 weeks. after 8 weeks, all patients will divide in 2 groups: Group 1 will recieve tDCS 10 sessions per 2 weeks and group 2 will receive placebo for 2 weeks. in Phase 2, the tDCS intervention will discontinue and PRT will continue on both groups for 2 weeks . All patients before and after the treatments will assess by Aberrant behavior checklist(ABC) and Vineland adaptive behavior test. Outcome variables: behavioral problems, adaptive functions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030532884N1**

Registration date: **2017-04-14, 1396/01/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

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Name of organization / entity

Hamadan University of Medical Scienses

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combining tDCS and behavioral intervention on behavioral problems in children with autism spectrum disorder

Public title
Effect of combining tDCS and behavioral intervention on children with autism spectrum disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Diagnosis of autism spectrum disorder based on the psychiatrist's interview or neuropediatrist According to DSM-5 criteria and using Gilliam autism rating scale(GARS). Be at least 10 and up to 16 years, weigh at least 5 Kg, Mental age be at least 18 months. Exclusion criteria: The people with acute and serious mental disorders such as schizophrenia, etc, People with other medical illnesses such as head injuries, Neurologic Diseases, A history of seizure, auditory and visual deficit.
Age
From **10 years** old to **16 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Scienses
Street address
Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Bulv
City
Vice Chancellor for Research and Technology, Hamadan University of Medical Scienses, Shahid Fahmideh
Postal code
Approval date
2017-02-18, 1395/11/30
Ethics committee reference number
IR.UMSHA.REC.1395.541

Health conditions studied

1

Description of health condition studied
Childhood autism
ICD-10 code
F84.0
ICD-10 code description
autistic psychopathy

Primary outcomes

1

Description
severity of behavioral problems
Timepoint
before and after the intervention
Method of measurement
aberrant behavior checklist

Secondary outcomes

1

Description
adaptive behavior
Timepoint
before and after the intervention
Method of measurement
Vineland test

Intervention groups

1

Description
Control Group - All patients will receive PRT for 8 weeks. after 8 weeks, Ṣubjects will will receive placebo tDCS for 2 weeks. in Phase 2, the tDCS intervention will discontinue and PRT will continue for 2 weeks
Category
Behavior

2

Description
Intervention Group- Patients will receive PRT for 8 weeks. after 8 weeks, subjects will recieve tDCS 10 sessions per 2 weeks. in Phase 2, the tDCS intervention will discontinue and PRT will continue for 2 weeks
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center

Hamadan University
Full name of responsible person
Mohammad Rezaei
Street address
Faculty of Rehabilitation Sciences, Hamadan University of Medical Sciences, Fahmideh Bulv
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Hamadan University of Medical Scienses
Full name of responsible person
Dr.Saeid Bashiriyan
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Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Bulv
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Hamadan
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, Hamadan University of Medical Scienses
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

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Mohammad Rezaei
Position
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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