# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**

Mohammad Rezaei

**Name of organization / entity**

Hamadan University of Medical Scienses

**Country**

Iran (Islamic Republic of)

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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, Ŝubjects 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
**Street address**
Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Bulv
**City**
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

**Contact**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*