Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparing the effectiveness of transcranial direct current stimulation treatment with common pharmacological treatments in autistic children's symptoms

Protocol summary

Study aim
Comparing the effectiveness of transcranial direct current stimulation treatment with common pharmacological treatments on autistic children

Design
A randomized, controlled, clinical trial with a parallel group design of 45 patients assigned into three groups (transcranial electrical stimulation intervention, pharmacological intervention, and sham intervention).

Settings and conduct
45 children with autism spectrum disorder are examined in Ardabil Fatemi Hospital as an intervention with tDCS stimulation, risperidone and placebo group and will be conducted in a double-blind design. The experimenter and the patient are blinded and are not aware of study. the experimenters who apply interventions are not aware of study hypotheses and the measurements will be carried out by independent experimenters who are blind to group assignment.

Participants/Inclusion and exclusion criteria
Inclusion: Diagnosis of autism spectrum disorder by a psychiatrist, being 6-16 years old required written iformed consent signed by parents, Exclusion: comorbidity with other neurodevelopmental disorders and neurological diseases

Intervention groups
Intervention group 1: TDCS intervention protocol consists of 10 sessions of 20 minutes of 1.5 mA electrical stimulation on consecutive days. Anodal electrode will be placed over the F3 and cathodal electrode will be placed over the Fp2. They will also receive placebo tablet (Galenus pharmaceutical company). Intervention group 2: Participants in this group will receive two daily Risperidone 1 mg tablets (Sobhan Pharmaceutical Company) for 10 consecutive days. sham stimulation Group: Participants in this group undergo 10 daily sessions of sham tDCS concurrent with placebo tablet (Galenus pharmaceutical company) for 10 consecutive days. (according to the protocol of the previous two groups.)

Main outcome variables
Clinical symptoms, executive functions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190917044793N1**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **retrospective**

Last update: **2020-10-15, 1399/07/24**
Update count: **0**

Registration date
2020-10-15, 1399/07/24

Registrant information

Name
Habibeh Ṡalvat
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-02, 1398/07/10

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of transcranial direct current stimulation treatment with common pharmacological treatments in autistic children’s symptoms

Public title
Transcranial electrical stimulation and pharmacological interventions in Autism Spectrum Disorder
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of autism spectrum disorder by a child psychiatrist being 6-16 years old required written iformed consent signed by parents
Exclusion criteria:
comorbidity with other neurodevelopmental disorders and neurological diseases
Age
From **6 years** old to **16 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be “simple randomization” (Suresh, 2011). This method randomization will be based on a single sequence of random assignments and include complete randomness of the assignment of patients to intervention groups (active tDCS group, pharmacology group, control group). Randomization will be done using an online website dedicated to randomizing sample size (https://www.randomizer.org/). By specifying the number of groups (n=3), the number of participants per group (n = 15), and the range of sample (1-45), participants will be randomly assigned to each group. Participants' code (1-45) will be randomly determined using draw. 45 children aged 6 to 16 with autism spectrum disorder that will be referred to the psychiatric clinic of Fatemi Hospital in Ardabil will receive one code upon referral using draw. Also, to prevent selective bias, the randomization method (for participants assignment) will be used and furthermore, concealment of random allocation will be applied.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study has a single-blind design. The care providers and outcome assessors are not aware of any type of pharmacological intervention or the state of electrical stimulation in patients. The investigators who determine intervention groups are independent from those experimenters who apply interventions and those who do the measurements and this will guarantee experimenters blindness for the electrical stimulation group (Gandinga et al., 2006) . For the patients, except those who are dedicated to pharmacological intervention, others in the electrical stimulation groups and control group are blind to the intervention. Patients in the real stimulation group, will not be aware of the stimulation condition (i.e., anodal stimulation vs sham stimulation). In patients assigned to control group, electrical stimulation includes 60 seconds of ramping up and down which induce sensations like the real stimulation, and participants are not expected to realize sham stimulation (Gandinga et al., 2006). These patients will be blind to the type of prescription drug as well as Risperidone and placebo are prepared entirely in one form (in terms of color, odor, and appearance).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ardabil University of Medical Sciences
Street address
End of University Street, Ardabil University of Medical Sciences
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Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Approval date
2017-03-07, 1395/12/17
Ethics committee reference number
IR.ARUMS.REC.1395.20

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Score in the Gilliam autism rating scale

Timepoint

before intervention and 5, 10 , 30 and 90 days after intervention

Method of measurement

Gilliam autism rating scale

2

Description

Performance in the verbal fluency task

Timepoint

before intervention and 5, 10 , 30 and 90 days after intervention

Method of measurement

Verbal fluency task

3

Description

Score in the theory of mind test

Timepoint

before intervention and 5, 10 , 30 and 90 days after intervention

Method of measurement

Theory of Mind Test (ToMT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: transcranial direct-current stimulation using an anodal electrode will be placed over left F3 and cathodal electrodes over right supraorbital F2 for 10 consecutive days, stimulation intensity will be 1.5 mA for 20 min per session. Additionally, they, along with electrical stimulation, will receive two placebo tablet 1 mg (Jalinoos Pharmaceutical company) per day (morning and noon). Measurements will take place before the intervention, and in 5, 10, 30, and 90 days after the intervention.

Category

Treatment - Devices

2

Description

Intervention Group 2: The pharmacological group will be examined by a child psychiatrist and undergo baseline measurement (pre-test). Then, as prescribed by specialists, 2 daily (morning and noon) tablets of 1 mg risperidone (manufactured by pharmaceutical Sobhan) will be taken for 10 consecutive days. Outcome measurements will be similar to the intervention group 1 and will take place before the intervention, after 5, 10, 30, and 90 days.

Category

Treatment - Drugs

3

Description

Control group: Participants in this group will receive a placebo tablet and concurrent sham tDCS with the same pharmacological regiment and stimulation montage for 10 days. Outcome measurements will take place before the intervention, after 5, 10, 30, and 90 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Psychiatry, Fatemi Hospital,

Full name of responsible person

Dr. Parviz Molavi

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Department of Psychiatry, Fatemi Hospital, Sareyn station, Ardabil

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the confidentiality of the participants' personal characteristics
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All collected data for the primary outcome measures only after anonymizing.
When the data will become available and for how long
starting 12 months after publication
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
To raise the level of knowledge about the treatment of autistic children
From where data/document is obtainable
Raw data and documents generated for this study are available from the corresponding authors and institution on reasonable request.
What processes are involved for a request to access data/document
A formal request from person/institutions should be sent the corresponding authors and corresponding institution via email (for international users) and mail (for national users).
Comments