Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Transcranial Directed Current Stimulation on upper limb function in children with unilateral cerebral palsy

Protocol summary

Study aim
Determining the effect of transcranial direct electrical stimulation technique on upper limb function of children with hemiplegic cerebral palsy

Design
Randomized clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients, lottery was used for randomization.

Settings and conduct
This study is conducted in the occupational therapy clinics of Karaj city. This study is a double-blind study in which the evaluator, the participants, and the statistician are unaware of the grouping. At first, preliminary tests are taken from all the samples by the evaluator. . Then the intervention sessions in such a way that one group called the control group did routine occupational therapy exercises for forty-five minutes in each session and the other group called the intervention group did occupational therapy exercises for forty-five minutes along with the technique of transcranial direct electrical stimulation of the area. An initial movement with a current intensity of 1.5-2 mV for twenty minutes in each session and for twenty sessions is started by the researcher and at the end the initial tests are taken again by the evaluator and then analyzed.

Participants/Inclusion and exclusion criteria
Subjects must have a diagnosis of hemiplegic cerebral palsy at the age of 5-10 years, have no unstable medical conditions such as seizures, and receive no other adjuvant treatment during the intervention.

Intervention groups
The intervention group receives 20 sessions of routine occupational therapy exercises for 45 minutes along with 20 minutes of electrical stimulation, and routine occupational therapy exercises are performed for 45 minutes in control group

Main outcome variables
motor function of the upper limb, dexterity of the upper limb, coordination of the upper limb-speed of the upper limb

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220725055552N1**
Registration date: **2022-07-27, 1401/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-27, 1401/05/05**
Update count: **0**

Registration date
2022-07-27, 1401/05/05

Registrant information

Name
Behnam Ghaderian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 26 3224 7828

Email address
behnamgh7491@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-26, 1401/05/04

Expected recruitment end date
2022-08-01, 1401/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Transcranial Directed Current Stimulation on upper limb function in children with unilateral cerebral palsy

Public title
The effect of electrical stimulation in the treatment of upper limbs of cerebral palsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The person must be a hemiplegic cerebral palsy The person must be 5-10 years old The person without unstable medical conditions such as seizures

Exclusion criteria:
Failure to attend more than one meeting. Non-cooperation of children and their families until the end of the regular study period

Age
From **5 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
To select the sample, we refer to Tanin and Nikan Karaj clinics, and fifty people will be sampled according to the conditions of inclusion in the study, but the samples will be divided into two intervention and control groups in a simple randomization using the coin toss method. In this way, we consider one of the groups to be the lion and the other group to be the line, and based on the desired sample size, the same number of coins are tossed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The evaluator, the participants and the statistician are unaware of the grouping, and also to blind the participants, devices and electrodes are placed for both groups, but stimulation is not done for the control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Damavand street

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2022-05-15, 1401/02/25

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.061

Health conditions studied

1

Description of health condition studied
Hemiplegia cerebral palsy

ICD-10 code
G80.2

ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Motor function of the upper limb

Timepoint
At the beginning of the intervention and after the end of the intervention

Method of measurement
Fugl-Meyer test

Secondary outcomes

1

Description
Upper limb coordination

Timepoint
The beginning and end of the intervention

Method of measurement
Bruininks-Oseretsky test

2

Description
Upper limb Integration

Timepoint
The beginning and end of the intervention

Method of measurement
Bruininks-Oseretsky test

3

Description
Precision of fine movement
Timepoint
The beginning and end of the intervention
Method of measurement
Bruininks-Oseretsky test

4

Description
Upper extremity speed
Timepoint
The beginning and end of the intervention
Method of measurement
Box and block test

5

Description
Dexterity of Upper extremity
Timepoint
The beginning and end of the intervention
Method of measurement
Bruininks-Oseretsky test

Intervention groups

1

Description
his group performed routine occupational therapy exercises for 45 minutes along with transcranial direct electrical stimulation technique, in which a low direct electric current with an intensity of 1.5-2 mV is injected into the primary motor area of the healthy hemisphere with a tDCS device. They receive for twenty minutes in each session and for twenty sessions in a period of one month.
Category
Rehabilitation

2

Description
Control group: This group receives routine occupational therapy exercises for forty-five minutes in each session and twenty sessions in a one-month period, and also to blind the participant, an electrical stimulation device is placed on the primary motor area of the healthy hemisphere for twenty minutes in each session. It can be done, but the stimulation does not take place.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Nikan Karaj Occupational Therapy Clinic
Full name of responsible person
Amir Abbas Parnoun
Street address
Republic Square, Amirkabir St
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3133654689
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2

Recruitment center
Name of recruitment center
Tanin Karaj Occupational Therapy Center
Full name of responsible person
Hirash ghaderian
Street address
Haft Tir Street, Ghasemi Street
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hirashybg87@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehdi Rezai
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rehabilitation.sbmu@gmail.com
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
no
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behnam Ghaderian
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
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Person responsible for updating data

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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