Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of transcranial direct current stimulation effect on gait in children with diplegic spastic cerebral palsy

Protocol summary

Study aim
assessing effect of anodal stimulation of Cz (motor cortical area) using tDCS on children with diplegic spastic cerebral palsy

Design
Randomized, double blind, sham controlled, crossover clinical trial on 20 diplegic spastic cerebral palsy children. Randomization was done with Sealed Envelope Ltd. 2021.

Settings and conduct
20 spastic-diplegic CP patients will be randomized in two groups of active and sham tDCS. Patients and investigators are blinded. In both groups pre-study evaluation and gait analysis will be done. Then 5 sessions of active or sham tDCS will be performed. All the evaluations and gait analysis will be repeated after one week. After one month of washout period the groups will be crossed and a course of tDCS will be performed. After one week all the evaluations will be repeated.

Participants/Inclusion and exclusion criteria
Patient with diplegic spastic cerebral palsy aging between 5 and 7 years will be included. Patients who have history of surgery in previous year, uncontrolled epilepsy, metallic foreign body in brain, needing urgent orthopedic surgery or cognitive problem troubling cooperation will be excluded.

Intervention groups
In intervention group direct electrical stimulation is performed using saline wet sponge; anode is placed on cortical motor area Cz and cathode is placed on forehead. There will be 30 seconds of ascending direct current at the beginning, thereafter 20 minutes of stable 2 mA current and at the end 30 seconds of descending current will be employed. In the sham (placebo) group ascending and descending currents will be employed at the beginning and the end but in the middle 20 minutes there will be no stimulation.

Main outcome variables
Gait velocity Gait cadence PEDI : Pediatric evaluation of disability inventory 6MWT: six minute walk test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170703034879N3**
Registration date: **2021-07-31, 1400/05/09**
Registration timing: **prospective**

Last update: **2021-07-31, 1400/05/09**
Update count: **0**

Registration date
2021-07-31, 1400/05/09

Registrant information

Name
Siamak Abdi

Name of organization / entity
Neurology department- shariati hospital- Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6650 1321

Email address
s-abdi@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of transcranial direct current stimulation effect on gait in children with diplegic spastic cerebral palsy

Public title

Effect of transcranial direct current stimulation in diplegic cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diplegic spastic cerebral palsy Gross Motor Function Classification System (GMFCS) less than 4, i.e. can walk independently or with walking aid age between 5 and 12 years

Exclusion criteria:

patient or parents do not consent history of surgery in previous 12 months uncontrolled epilepsy metallic foreign body in brain orthopedic problem needing urgent surgery cognitive problem troubling cooperation

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use computer-generated randomization. Five blocks of 4 will be made by third party not involving in the study and randomization list will be generated. Neither investigator nor patients know the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

A third party will make randomization list. The list will be given to investigator. Investigator, occupational therapist, outcome assessor and patients are blinded to the groups. After completion of study blinding will be removed. Data analyzer will not be blinded to the groups.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Neurology department, Shariati Hospital, North Kargar Street

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.354

Health conditions studied

1

Description of health condition studied

spastic diplegic Cerebral palsy

ICD-10 code

G80.1

ICD-10 code description

Spastic diplegic cerebral palsy

Primary outcomes

1

Description

velocity of gait

Timepoint

gait velocity will be measured 1 week after the completion of first and second course (after crossover) of tDCS

Method of measurement

Measured during gait analysis by velocity sensors

Secondary outcomes

1

Description

cadence

Timepoint

cadence will be measured 1 week after the completion of first and second course (after crossover) of tDCS

Method of measurement

Measured during gait analysis by velocity and time sensors

2

Description
PEDI : Pediatric evaluation of disability inventory
Timepoint
PEDI will be filled 1 week after the completion of first and second course (after crossover) of tDCS
Method of measurement
The investigator will fill the inventory.

3

Description
6MWT: six minute walk test
Timepoint
6MWT be measured 1 week after the completion of first and second course (after crossover) of tDCS
Method of measurement
The distance walked in 6 minutes will be measured by the investigator.

Intervention groups

1

Description
Intervention group: In intervention group direct electrical stimulation is performed using saline wet sponge; anode is placed on cortical motor area Cz and cathode is placed on forehead. There will be 30 seconds of ascending direct current at the beginning, thereafter 20 minutes of stable 2 mA current and at the end 30 seconds of descending current will be employed.
Category
Treatment - Devices

2

Description
Category
empty

3

Description
Control group: In the sham group direct electrical stimulation is performed using saline wet sponge; anode is placed on cortical motor area Cz and cathode is placed on forehead. There will be 30 seconds of ascending direct current at the beginning, in the next 20 minutes no current is employed. Thereafter 30 seconds of descending current will be employed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Siamak Abdi
Street address
Neurology department, Shariati Hospital, North Kargar Street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammadali Sahraeian
Street address
Neurology department, Shariati Hospital, North Kargar Street
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person

Dr Siamak Abdi

Position
Associate professor of neurology

Latest degree
Specialist

Other areas of specialty/work
Neurology

Street address
Neurology department, Shariati hospital, Jalal-e-Al-e-Ahmad Hwy

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Person responsible for updating data

Contact

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
No - There is not 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

Title and more details about the data/document
Deidentified IPD data collected for the primary and secondary outcomes will be available.

When the data will become available and for how long
Deidentified IPD data will be available 1 year after publication.

To whom data/document is available
Deidentified IPD data will be available for people working in academic institutions.

Under which criteria data/document could be used
Request coming to principal investigator, will be evaluated. Requests that are to be used in review article or meta-analysis will be accepted.

From where data/document is obtainable
Data request can reach the principal investigator through email; siamak.abdi@yahoo.com. Phone number +989363813113 can be used for text messages.

What processes are involved for a request to access data/document

Research ethics committee certificate is needed to be enclosed in the request email. Your email will be answered within a week. If you receive no answer within a week, another email as reminder is recommended.

Comments