

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2224

Email

Siamak.Abdi@yahoo.com

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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2224

Email

Siamak.Abdi@yahoo.com

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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2224

Fax

+98 21 8863 3039

Email

Siamak.Abdi@yahoo.com

Web page address

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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2224

Fax

+98 21 8863 3039

Email

Siamak.Abdi@yahoo.com

Web page address

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2224

Fax

+98 21 8863 3039

Email

Siamak.Abdi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Siamak Abdi

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