

# 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**

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**