

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Study the effect of cathodal tDCS on healthy side comparing with anodal tDCS on affected side of motor cortex on lower limb muscles spasticity in patients with stroke

#### Protocol summary

##### Study aim

Determining the effect of cathodal TDCS on the healthy side compared to anodal TDCS on the affected side of the motor cortex on spasticity of lower limb muscles, balance and quality of life of stroke patients

##### Design

RCT with parallel groups of random grouping in block method where 45 stroke patients are placed in three groups: cathodal, anodal and control.

##### Settings and conduct

this study will take place at Neuromuscular Rehabilitation Research Center, Semnan University of Medical Sciences. After randomization, 45 chronic stroke patients will be divided into three groups: cathodal, anodal, and control. First, the variables of the study will be evaluated in all subjects, and then all three groups will receive ten sessions of routine physiotherapy treatment. In addition to routine treatment, the cathodal and anodal groups received cathodal TDCS and anodal TDCS treatment, respectively. At the end of the tenth session and two weeks after that, all variables are evaluated again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Stroke patients 40 to 80 years old At least 6 months have passed since the stroke The minimum Ashworth score is 1. Criteria for not entering the study: History of epilepsy, cerebellar aneurysm, head injury Metal implants in the brain Widespread infection Severe flaccid hemiplegia Renal or hepatic impairment Severe cognitive impairment Stroke of both hemispheres

##### Intervention groups

cathodal group: 10 routine sessions of stroke physiotherapy+cathodal TDCS anadol group: 10 routine sessions of stroke physiotherapy+ anodal TDCS control group: 10 routine sessions of stroke physiotherapy

##### Main outcome variables

Spasticity of ankle plantar flexor muscles during active and passive ankle dorsiflexion, balance, quality of life

before the first session, at the end of the tenth session and two weeks after the last treatment session

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230104057044N1**

Registration date: **2023-01-27, 1401/11/07**

Registration timing: **prospective**

Last update: **2023-01-27, 1401/11/07**

Update count: **0**

##### Registration date

2023-01-27, 1401/11/07

##### Registrant information

##### Name

Raziyeh Bazghandi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4562 5342

##### Email address

razi\_bazghandi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-07-23, 1402/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Study the effect of cathodal tDCS on healthy side comparing with anodal tDCS on affected side of motor cortex on lower limb muscles spasticity in patients with stroke

**Public title**  
Investigating the effect of tDCS on stroke

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Stroke patients with an age range of 40 to 80 years At least 6 months have passed since the stroke No history of botulism injections or other invasive treatments in the past 6 months The minimum Ashworth score is 1.

**Exclusion criteria:**

History of epilepsy History of cerebellar aneurysm Metal implants in the brain Widespread infection (all areas of the middle cerebral artery) Severe flaccid hemiplegia head injury Other neurological or orthopedic diseases that can affect motor function Renal or hepatic impairment Report of injection of previous painkillers Severe cognitive impairment The stroke areas involve both hemispheres

**Age**  
From **40 years** old to **80 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **45**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The grouping method is a random grouping type in the block method where people are placed in three groups. The size of the used block is 3 and therefore, based on this, the combination of these modes for the control group and the patient groups, which are displayed with the letters C, T1 and T2 respectively, will include 6 modes. which will include (T2T1C, T1T2C, T1CT2, CT2T1, and CT1T2, T2CT1, ). The selection of blocks will be done randomly with the help of Excel software so that 15 blocks are randomly selected and therefore 45 samples can be included in the study in a random sequence that can be included in each control and treatment group. The number of blocks and how they are executed are done by hiding them inside the envelope. In this method, the blocks are numbered based on a random sequence and placed inside the envelopes, and the researcher assigns them to the intervention and treatment groups based on the order of arrival of the patients.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethics Committee of Semnan University of Medical Sciences

**Street address**

Treatment and Medical Education headquarters, Ministry of Health, between South Flamak and Zarafshan, Simai Iran St, Qods town

**City**

Tehran

**Province**

Tehran

**Postal code**

2188363600

**Approval date**

2022-12-26, 1401/10/05

**Ethics committee reference number**

IR.SEMUMS.REC.1401.230

**Health conditions studied**

**1**

**Description of health condition studied**

stroke

**ICD-10 code**

I64

**ICD-10 code description**

Stroke, not specified as haemorrhage or infarction

**Primary outcomes**

**1**

**Description**

The grade of spasticity in ankle plantar flexor muscles during active and passive ankle dorsiflexion

**Timepoint**

Before intervention, after the tenth session of the intervention, two weeks after the last session of the intervention

**Method of measurement**

Modified Ashworth scale and electromyography device

**2**

**Description**

Balance

### **Timepoint**

Before intervention, after the tenth session of the intervention, two weeks after the last session of the intervention

### **Method of measurement**

Berg balance scale

## **3**

### **Description**

Quality of life

### **Timepoint**

Before intervention, after the tenth session of the intervention, two weeks after the last session of the intervention

### **Method of measurement**

WHOQOL-BREF

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: cathodal. It includes ten sessions of routine stroke physiotherapy along with cathodal TDCS. In this study, the TDCS device (ActivaDose® II, ActivaTeK™ Inc., Gilroy, CA) will be used. The size of stimulation electrodes are 5 x 7 cm and are made of sponge soaked in salt solution. The anode (+) electrode will be placed on the un-affected area of the brain and the reference electrode will be placed on the opposite circuit. In the cathodal group, cathodal TDCS with an intensity of 2 mA will be used for 20 minutes on the motor cortex of the un-affected side, and along with it, the contraction of the tibialis anterior muscle will be applied through functional electrical stimulation current (6 seconds of contraction and 12 seconds of rest). The duration of each physiotherapy session will be 40 minutes. In the first ten minutes, ankle plantar flexor muscle stretching exercises will be performed with 20 repetitions and each stretch for 20 seconds. Then, TDCS cathodal treatment will be used along with FES, and at the end, the patient will be given training on the postural correction, corrective and functional exercises, and balance exercises to perform exercises at home. Treatment sessions will be conducted in 5 sessions per week and for a total period of 2 weeks.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Intervention group: anodal. It includes ten sessions of routine stroke physiotherapy along with anodal TDCS. The device used and the size of the stimulation electrode in this group will be similar to the cathodal group. In this group, the anode (+) electrode will be placed on the

affected area of the brain and the reference electrode will be placed on the opposite circuit. In this group, anodal TDCS with an intensity of 2 mA will be applied for 20 minutes on the motor cortex of the affected side along with the contraction of the tibialis anterior muscle through functional electrical stimulation current (6 seconds of contraction and 12 seconds of rest). The duration of each session will be 30 minutes. In the first ten minutes, stretching exercises for the ankle plantar flexor muscles will be performed with 20 repetitions and each stretch for 20 seconds. Then TDCS anodal treatment along with FES will be used and at the end, the patient will be taught the correct position of the body, corrective and functional exercises and balance exercises to perform exercises at home. Treatment sessions will be conducted in 5 sessions per week and for a total period of 2 weeks.

#### **Category**

Rehabilitation

### **3**

#### **Description**

Control group: In this group, ten routine stroke physiotherapy sessions will be performed. Routine physiotherapy includes maintaining the correct position of the body, stretching exercises, functional electrical stimulation current, physiotherapy techniques and exercise training. The FES current will be applied through two rubber adhesive electrodes of 5 cm<sup>2</sup> size placed on the movement point of the tibialis anterior muscle. Active FES was set with a pulse length of 250 μs, a frequency of 50 Hz, and a stimulation period of 1:2 with active muscle contraction during 6 s. The total duration of the stimulation will be 20 minutes. The treatment sessions will be 5 sessions per week for a total period of 2 weeks.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

##### **Full name of responsible person**

Raziyeh Bazghandi

##### **Street address**

Taba Tabai Clinic, Next to Nemat Ice Cream, Qods Boulevard

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Semnan

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##### **Postal code**

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##### **Email**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Majid mir Mohammad Khani

**Street address**

Deputy of Research and Technology, Headquarter of Semnan University of Medical Sciences and Health Services, Basij Blvd

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rds@semums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

**Full name of responsible person**

Fatemeh Ehsani

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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rehabilitation school of Semnan University of Medical Sciences

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## Person responsible for scientific inquiries

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**Position**

Associate Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

**Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Raziyeh Bazghandi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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No. 3, Imam Khomeini 15., Imam Khomeini Ave.

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+98 51 4562 5342

**Fax****Email**

## 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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

### When the data will become available and for how long

The access period starts 6 months after the results are published

### To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions.

### Under which criteria data/document could be used

The data of this study will be available for meta-analysis.

### From where data/document is obtainable

fatemehehsani59@yahoo.com

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

In order to request the data of this study, it is necessary to send an official written request by e-mail and clearly explain the reason for the request.

### Comments