# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effects of short-term and long-term anodal tDCS over M1 cortex with routine physiotherapy on spasticity and activity of plantar flexor muscles in stroke patients

## Protocol summary

**Study aim**
The effects of short-term and long-term anodal tDCS over M1 cortex with routine physiotherapy on spasticity and activity of plantar flexor muscles in stroke patients

**Design**
The clinical trial with a control group, community-based and pragmatic, with parallel groups, randomized, without control with placebo, single center trial.

**Settings and conduct**
Neuromuscular Rehabilitation Research Center.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients stroke 40 to 80 years old; 3 weeks to 6 months of Stroke past: No history of botulism injection. Exclusion criteria: Renal or hepatic impairment; Damage to the head; History of the cerebrovascular aneurysm; History of epilepsy; The stroke areas have affected both hemispheres.

**Intervention groups**
Intervention group: According to the treatment protocol, direct transcranial flow stimulation (tDCS) is applied to the affected motor cortex and routine physiotherapy is performed for patients. Control group: Based on the treatment protocol, placebo stimulation and routine physiotherapy for patients.

**Main outcome variables**
Activation and intensity of muscle contraction

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20151228025732N39**
Registration date: **2019-05-23, 1398/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-23, 1398/03/02**
Update count: **0**

**Registration date**
2019-05-23, 1398/03/02

**Registrant information**

**Name**
Alireza Emadi

**Name of organization / entity**
Semnan University of Medical Sciences, Semnan, Iran

**Country**
Iran (Islamic Republic of)

**Phone**
+98 23 3345 1336

**Email address**
are20935@semums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-05-21, 1398/02/31

**Expected recruitment end date**
2020-05-20, 1399/02/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effects of short-term and long-term anodal tDCS over M1 cortex with routine physiotherapy on spasticity and activity of plantar flexor muscles in stroke patients

**Public title**
The effects of short-term and long-term anodal tDCS over M1 cortex with routine physiotherapy on spasticity and activity of plantar flexor muscles in stroke patients

**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients stroke 40 to 80 years old 3 weeks to 6 months of Stroke past No history of botulism injection
**Exclusion criteria:**
Renal or hepatic impairment Damage to the head History of cerebrovascular aneurysm History of epilepsy The stroke areas have affected 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: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple randomization, individual, packed envelope.
**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**
Ethics committee of Semnan University of Medical Sciences
**Street address**
Semnan University of Medical Sciences, Basij Blvd, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Approval date**
2019-05-22, 1398/03/01
**Ethics committee reference number**
IR.semums.REC.1398.030

## Health conditions studied

### 1

**Description of health condition studied**
Stroke
**ICD-10 code**
Z82.3
**ICD-10 code description**
Family history of stroke

## Primary outcomes

### 1

**Description**
Activation and intensity of muscle contraction
**Timepoint**
Immediately after the intervention and 1 month after the intervention
**Method of measurement**
Electromyography (EMG)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: According to the treatment protocol, direct transcranial flow stimulation (tDCS) is applied to the affected motor cortex and routine physiotherapy is performed for patients.
**Category**
Rehabilitation

### 2

**Description**
Control group: Based on the treatment protocol, placebo stimulation and routine physiotherapy for patients.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Neuromuscular Rehabilitation Research Center
**Full name of responsible person**
Fatemeh Ehsani
**Street address**
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
**City**
Semnan
**Province**
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**Postal code**

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**Email**
fatemehehsani59@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Parviz Kokhaei
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P_kokha@yahoo.com
**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
-
**When the data will become available and for how long**
-
**To whom data/document is available**
Only available to scholars working in academic institutions.
**Under which criteria data/document could be used**
In case of relevant studies.
**From where data/document is obtainable**
Fatemeh Ehsani Neuromuscular Rehabilitation Research Center, Ghods Blvd. +98 9191310755
**What processes are involved for a request to access data/document**
-
**Comments**