

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of short-term and long-term anodal tDCS over M1 cortex with routine physiotherapy on spasticity and activity of wrist 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 wrist 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: **IRCT20151228025732N38**

Registration date: **2019-04-01, 1398/01/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-01, 1398/01/12**

Update count: **0**

Registration date

2019-04-01, 1398/01/12

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-17, 1397/04/26

Expected recruitment end date

2019-07-16, 1398/04/25

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 wrist 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 wrist 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

2018-07-17, 1397/04/26

Ethics committee reference number

IR.SEMUMS.REC.1397.081

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.

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fatemehehsani59@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

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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

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

Semnan University of Medical Sciences

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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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Sara Halacu

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

n 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