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 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

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Iran (Islamic Republic of)

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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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Semnan
Province
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fatemehehsani59@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 updating data

Contact

Name of organization / entity
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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