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

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Iran (Islamic Republic of)

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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

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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 cm2 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

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Sponsors / Funding sources

1

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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

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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