Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluating the effects of a single session unihemispheric concurrent dual-site transcranial direct currents of primary cortex-dorsolateral prefrontal cortex on upper extremity motor performance in patients with subacute stroke

Protocol summary

Summary

Objectives: Effects of Anodal- Transcranial Direct Current Stimulation, Unihemispheric Concurrent Dual-Site (a-tDCSUCDS) on upper limb motor performance in individuals with stroke has not been clearly evaluated yet. Therefore, the purpose of the present study was to evaluate the effects of a-tDCSUCDS of primary motor cortex and dorsolateral prefrontal cortex (M1-DLPFC) on the upper limb motor performance in patients with subacute stroke. Design: A single blind, before-after study, single arm study Methods: a-tDCSUCDS is a new tDCS technique in which two active electrodes from two separated channels are placed unilaterally over two functionally related target sites, i.e. primary cortex (M1) and dorsolateral prefrontal cortex (DLPFC). In this technique the cathode electrodes are positioned over the contralateral supraorbital area. Thirteen patients suffering from subacute stroke will participate in three sessions of testing receiving three different experimental conditions in random order: twenty minutes of conventional a-tDCS of M1, 20 minutes of a-tDCSUCDS of M1-DLPFC, and 20 minutes sham a-tDCSUCDS of M1-DLPFC. Washing out period: 72 hours Outcome measures: Fugl meyer assessment tool, 9 pin Pegboard performance (time to completion), and reaction time custom designed software to evaluate the upper extremity reaction time. All these outcomes will be measured before, immediately after and 30 minutes after the application of a-tDCSs. Inclusion criteria: first stroke, subacute stroke, communication ability, spasticity of 3 or lesser on modified Ashworth scale, no botulinum injection in last 3 months, and memory or cognitive disorders. Exclusion criteria: any pain or discomfort during the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012520787N1**
Registration date: **2015-09-16, 1394/06/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name

Leila Rahnama

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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+98 21 2218 0039

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Recruitment status

Recruitment complete

Funding source

Private resources.

Expected recruitment start date

2015-09-21, 1394/06/30

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of a single session unihemispheric concurrent dual-site transcranial direct currents of primary cortex-dorsolateral prefrontal cortex on upper extremity motor performance in patients with subacute stroke

Public title

Effects of transcranial direct currents on motor performance in patients with stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: first stroke, subacute stroke (1-6 months after stroke), communication ability , and mild to moderate hemiparesis, spasticity of 3 or less on modified Ashworth scale, no botulinum injection in last 3 months, no memory or cognitive disorders, no deformity or contractures in upper extremities, no pacemaker, no narcotic addiction, no psychological problems and signing the informed consent form. Exclusion criteria: Patient’s unwillingness to participate or continue the study, Convulsion and reporting pain or discomfort during the intervention.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **13**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

A single arm study in which each participant receives all 3 types of interventions with wash out period of 72 hours. Single blind in a way that patients were not aware whether they receive real tDCS or the sham.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Koudakyar St., Daneshjou Blvd., Evin

City

Tehran

Postal code

1985713834

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

IR.USWR.REC.1394.6

Health conditions studied

1

Description of health condition studied

Stroke (Cerebrovascular accident)

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Reaction time

Timepoint

Before intervention, immediately and 30 minutes after, (72 h interval among different interventions)

Method of measurement

Custom made software

2

Description

Time of performance

Timepoint

Before intervention, immediately and 30 minutes after, (72 h interval among different interventions)

Method of measurement

9-pin peg board

3

Description

Motor performance

Timepoint

Before intervention, immediately and 30 minutes after, (72 h interval among different interventions)

Method of measurement

Fugl-Meyer Assessment

Secondary outcomes

empty

Intervention groups

1

Description

Thirteen patients suffering from subacute stroke will participate in three randomly selected sessions of testing receiving three different experimental conditions including: twenty minutes of conventional anodal transcranial direct current of primary motor cortex, 20 minutes of anodal unihemispheric concurrent dual-site transcranial direct current of primary motor cortex-dorsolateral prefrontal cortex and 20 minutes sham anodal unihemispheric concurrent dual-site transcranial direct current of primary motor cortex-dorsolateral prefrontal cortex. Therefore, each participant receives two types of transcranial direct current and a session of sham. As for anodal unihemispheric concurrent dual-site transcranial direct current, two active electrodes from two separated channels are placed unilaterally over two functionally related target sites, i.e. primary cortex and dorsolateral prefrontal cortex . In this technique the cathode electrodes are positioned over the contralateral supraorbital area.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation Hospital

Full name of responsible person

Amir Hossein Kahlaei

Street address

Nemati St., Shahid Soleimani Ave., Gheitarieh

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2

Recruitment center

Name of recruitment center

Asma Rehabilitation Center

Full name of responsible person

Marzieh Afkhami

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Number 20 St., Yousefabad Ave.

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3

Recruitment center

Name of recruitment center

Akhavan Rehabilitation Center

Full name of responsible person

Leila Rahnama

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Asadimanesh St., Near Monirieh Sq., Valiasr Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. Hamid-Reza Khankeh

Street address

Vice Chancellor for Research, University of Social Welfare and Rehabilitation Sciences, Koudakyar St., Daneshjou Blvd., Evin

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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

Vice Chancellor for Research, University of Social Welfare and Rehabilitation Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

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Position

Master of Science student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty