

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effects of Transcranial direct current stimulation (tDCS) Combined with balance training on postural control and spasticity in chronic stroke patients (A Randomized Controlled Trial)

Protocol summary

Summary

Balance impairment and fear of falling negatively impact function of stroke patients. These can be addressed through a tDCS intervention. To identify combinations effects of tDCS stimulation and balance training on balance control in chronic stroke patients, leg motor area will be stimulated using anodal tDCS. In this study intervention group will be Offered Anodal tDCS brain stimulation (20 minutes, 2 mA) and balance training (10-15 minutes) for 5 consecutive days, and in control group participants will receive 5 days sham tDCS and balance training (10-15 minutes). Based on Offered sample size estimation is 20 chronic stroke patients. The patients will be assessed before and after 5 sessions of intervention. After intervention Analysis of postural control using nonlinear methods, in the structure of the time series of the COP using Approximate entropy and Berg balance scale, modified Ashworth and H-reflex latency will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121715840N1**

Registration date: **2015-06-28, 1394/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-28, 1394/04/07

Registrant information

Name

Fariba Yadolahi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 9900

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahid Beheshti university of Medical sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2016-02-28, 1394/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Transcranial direct current stimulation (tDCS) Combined with balance training on postural control and spasticity in chronic stroke patients (A Randomized Controlled Trial)

Public title

Transcranial direct current stimulation (tDCS) and balance rehabilitation in stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age ≥ 18 years: first ischemic stroke: chronic stroke (6 months after stroke): romberg test > 30 second: not using Botax: for spasticity Exclusion

criteria: Other neurological conditions that affect balance; use of any neuro- or psycho-active medications that alters balance; ongoing/recent (within 3 months) balance rehabilitation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak St. , Shahid Chamran Highway

City

Tehran

Postal code

Approval date

2015-01-04, 1393/10/14

Ethics committee reference number

sbmu.irc.1393.500

Health conditions studied

1

Description of health condition studied

cerebro vascular disease(stroke)

ICD-10 code

166.1

ICD-10 code description

Occlusion and stenosis of anterior cerebral artery

Primary outcomes

1

Description

postural control

Timepoint

Before intervention-after intervention

Method of measurement

Approximate entropy

Secondary outcomes

1

Description

Spasticity

Timepoint

Before and after intervention

Method of measurement

Modified Ashworth scale and H-reflex

Intervention groups

1

Description

Intervention group: Brain stimulation with anodal tDCS (20 min, 2 mA) and balance training for five consecutive days

Category

Rehabilitation

2

Description

Control group: Will be offered sham tDCS with five consecutive days balance training .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar Hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Physical Therapy Clinic, Shahid Beheshti University of Medical sciences

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr. Mino Khalkhali zavieh

Street address

Faculty of Rehabilitation, across from Bo-Ali Hospital,
Damavand Street

City

Tehran

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 of Shahid Beheshti
University of Medical 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Fariba Yadollahi

Position

MD-MPH-PhD

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