

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effectiveness of transcranial direct current stimulation (TDCS) on the swallowing function of the patients with post - stroke dysphagia

Protocol summary

Study aim

Investigating the effectiveness of transcranial direct current stimulation (TDCS) on the swallowing function of the patients with post-stroke dysphagia

Design

A double blinded concealed clinical trial, parallel group, randomized, with 48 participants and control group.

Settings and conduct

The study will be conducted in Shiraz University of Medical Sciences hospitals. Stroke patients will be screened and assessed and will put into control or experimental group. They will get intervention for 5 sessions and will be assessed one day after the last day of intervention and one month later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 or over. Presence of ischemic stroke confirmed with brain imaging. having dysphagia according to Northwestern Dysphagia Patient Checklist Screening tool (NDPCS). Exclusion criteria: Hemorrhagic or Lacunar stroke. Previous history of dysphagia. Presence of neurological disorders other than stroke or neurodegenerative disorders. Auditory and Visual Condition interfering with a speech therapist or assessor or TDCS technician's instruction. History of seizures. Those with a cardiac pacemaker or metallic implants. Previous history of skull surgery or current need of skull surgery. Presence of a tracheal cannula. Unstable medical condition which can interfere with the study process (such as hemodynamic instability, decreased level of consciousness, etc.) Inability to stay alert during the treatment. For the safety of both patients and the research group, none of the patients recruited for the study had active SARS-COV-2 infections or a history of infection in the last 14 days.

Intervention groups

The experimental group will receive both behavioral treatment and TDCS. The control group will receive the

behavioral treatment and the sham TDCS

Main outcome variables

The functional oral intake; dysphagia severity; aspiration severity

General information

Reason for update

Dictation mistakes, Add some example/sentences for more clarification

Acronym

IRCT registration information

IRCT registration number: **IRCT20200520047521N1**

Registration date: **2020-10-30, 1399/08/09**

Registration timing: **prospective**

Last update: **2022-05-28, 1401/03/07**

Update count: **1**

Registration date

2020-10-30, 1399/08/09

Registrant information

Name

Sima Farpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3639 9507

Email address

sima.farpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-20, 1399/08/30

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of transcranial direct current stimulation (TDCS) on the swallowing function of the patients with post – stroke dysphagia

Public title
Effectiveness of transcranial direct current stimulation (TDCS) in the patients with post – stroke dysphagia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years or over. Presence of ischemic stroke confirmed with brain imaging. diagnosis of dysphagia according to Northwestern Dysphagia Patient Checksheet Screening tool (NDPCS).
Exclusion criteria:
Hemorrhagic or Lacunar stroke. Previous history of dysphagia. Presence of neurological disorders other than stroke or neurodegenerative disorders. Auditory and Visual Condition interfering with a speech therapist or assessor or TDCS technician's instruction History of seizures. Those with a cardiac pacemaker or metallic implants. Previous history of skull surgery or current need of skull surgery. Presence of a tracheal cannula. Unstable medical condition which can interfere with the study process (such as hemodynamic instability, decreased level of consciousness, etc.) Inability to stay alert during the treatment. This study was done during the COVID- 19 pandemic. For the safety of both patients and the research group, none of the patients recruited for the study had active SARS- COV- 2 infections or a history of infection in the last 14 days.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified randomisation using permuted blocked randomisation in each group. With random allocation software. Severity of dysphagia and severity of stroke will be used for grouping. Using sealed envelopes by a

secretary for concealment.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding participants/ families/ caregivers: All participants will receive behavioral swallowing therapy and TDCS stimulation. For the sham group (control group) the same montage of TDCS will be performed. The only difference is that the real group (experimental group) will receive 20 minutes of TDCS stimulation while the sham group will receive the current only for 30 seconds at the beginning and the end of the period . Blinding care providers (speech therapist, and stroke physicians), investigators and outcome assessor: The TDCS technician will be trained and employed to deliver the TDCS . The technician will be independent of the investigators and will be unaware of the study' methodology. The secretary will inform them about the group of the patients (real or sham TDCS) in a sealed envelope. Therefore, the only persons who will know the group of the patients (sham or real) will be the secretary and the technician of TDCS.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman neuroscience research center, No.1 Alley, Jihad Ave., Somayye crossroad

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.KMU.REC.1399.366

Health conditions studied

1

Description of health condition studied

DYSPHAGIA POST- STROKE

ICD-10 code

R13

ICD-10 code description

Aphagia and dysphagia

Primary outcomes

1

Description

The feeding status of the patient with the Functional Oral Intake Scale (FOIS)

Timepoint

before intervention, one day after the last day of intervention, one month after intervention

Method of measurement

Functional Oral Intake Scale (FOIS)

Secondary outcomes

1

Description

the severity of dysphagia and aspiration

Timepoint

before intervention, one day after the last day of intervention, one month after intervention

Method of measurement

The MANN assessment of swallowing ability (MASA)

Intervention groups

1

Description

Intervention group: TDCS online with classic (behavioral) swallowing therapy for 20 minutes in five therapy sessions (1 session each day)

Category

Rehabilitation

2

Description

Control group: Sham TDCS online with classic (behavioural) swallowing therapy for 20 minutes in five therapy sessions (1 session each day)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Dr. Afshin Borhani Haghighi

Street address

Namzi hospital, Zand street

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7193613311

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

Shahid Rajaei (Emtyaz) hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

Shahid Chamran hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Majid Asady Shekary

Street address

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7619813159

Phone

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Email

m_asady@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Sima Farpour

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Position

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Latest degree

Master

Other areas of specialty/work

Neuroscience

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participant data will be shared after the encoding including age, sex, dysphagia severity, test results and research implementation method.

When the data will become available and for how long

Six month after publication the results will be shared.

To whom data/document is available

All researchers.

Under which criteria data/document could be used

To use in meta- analysis studies or citation data in other relevant studies.

From where data/document is obtainable

Sima Farpour email: sima.farpour@gmail.com Mobile: 0098 9173177636

What processes are involved for a request to access data/document

By formal request via email and the purpose of using data, the information will be sent.

Comments