Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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 orTDCS 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

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Iran (Islamic Republic of)

Phone
+98 71 3639 9507

Email address
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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 orTDCS 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 begining 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, Jahad 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
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Recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 updating data

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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