Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of combined transcranial Direct Current Stimulation (tDCS) and conventional swallowing therapy on improvement of the swallowing disorder in persons with Parkinson’s disease

Protocol summary

Study aim

The effectiveness of combined transcranial Direct Current Stimulation (tDCS) and conventional swallowing therapy on improvement of the swallowing disorder in persons with Parkinson’s disease

Design

A randomized, double-blinded, sham-controlled clinical trial with a parallel group design

Settings and conduct

This research will be carried out in three phases: first phase (design of the tDCS protocol), second phase (pilot study) and third phase (intervention). In the first phase, the design of the protocol and tDCS parameters will take place. In dead, parameters such as duration of stimulation, stimulation intensity, the number of stimulation sessions, bilateral or one-side stimulation and stimulation location are determined in this phase. In the second phase, the presentation of the tDCS parameters, including the position of the electrodes, the stimulus intensity, the duration of the stimulation, and the number of treatment sessions, are evaluated. Finally, in the third phase, individuals will be invited to the Tehran University of Medical Sciences, rehabilitation faculty if they have inclusion criteria and consent to participate in the study. Then, in order to receive the intervention, a randomized blocking method is used to the assignment of participants to the groups.

Participants/Inclusion and exclusion criteria

Parkinson's disease; diagnosis of dysphagia; aged over 18 years old; no implant or electrode in the head due to deep brain stimulation; non-pregnancy of the subject.

Intervention groups

1. An intervention group that receives a combined treatment of transcranial Direct Current Stimulation and conventional swallowing therapy. 2. The control group that receives conventional swallowing therapy.

Main outcome variables

Dysphagia; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190412043248N1**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name

Aliakbar Dashtelei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of combined transcranial Direct Current Stimulation (tDCS) and conventional swallowing therapy on improvement of the swallowing disorder in persons with Parkinson’s disease

Public title
Effect of brain stimulation on the improvement of swallowing disorder in Parkinson's patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Parkinson's disease with swallowing disorder Not having an implants Being patient in the On phase Age over 18 years Not having a history of dysphagia Non-pregnancy of subjects
Exclusion criteria:
The occurrence of any other neurological disorder (such as stroke, seizure, epilepsy, etc.) during the conduct of the research After the study begins, the implant needs to be used Do not cooperate Getting pregnant
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment by blocks: At this stage, 20 blocks were used. Therefore, each subject by random selection of one of these blocks is placed in one of two groups. So, randomly, there will be 10 subjects in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Unawareness of the participants and the evaluator of the outcomes about the groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Rehabilitation Faculty, Tehran University of Medical Sciences Pitch-e-Shemiran, Enghelab Ave., Tehran-IR
City
Tehran
Province
Tehran
Postal code
1148956111
Approval date
2019-01-02, 1397/10/12
Ethics committee reference number
IR.TUMS.FNM.REC.1397.179

Health conditions studied

1

Description of health condition studied
Parkinson
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Dysphagia score in aspiration-penetration scale
Timepoint
At the beginning of the sampling, after the last intervention session and one month after the last intervention session
Method of measurement
Fiberoptic endoscopic evaluation of swallowing (FEES) and aspiration-penetration scale

Secondary outcomes

1

Description
Dysphagia handicap index and swallowing disturbance questionnaire
Timepoint
At the beginning of the sampling, after the last intervention session and one month after the last intervention session
Method of measurement
Swallowing Disturbance Questionnaire

2

Description

Dysphagia Handicap Index

Timepoint

At the beginning of the sampling, after the last intervention session and one month after the last intervention session

Method of measurement

Dysphagia Handicap Index

Intervention groups

1

Description

Combined treatment group: Patients in this group receive anodal stimulation of tDCS with conventional treatment for 30 minutes. The anodal-tDCS with a 1 mA intensity is inserted bilaterally into the pharyngeal motor cortex in the left and right hemisphere. Conventional swallowing treatment is a protocol of rehabilitation and compensatory treatments. This protocol will be obtained according to the clinical evaluation results of swallowing. Rehabilitation treatment includes swallowing maneuvers (Mendelsohn maneuver, supraglottic swallowing maneuver, super-supraglottic swallowing maneuver, and effortful swallow), oral-motor exercises, and Thermal-tactile stimulation. Compensatory methods will also include adjusting the volume, velocity, and speed of food delivery and postural techniques.

Category

Rehabilitation

2

Description

sham treatment group: In the sham-tDCS group, patients first receive tDCS stimulation for 30 seconds with an intensity of 1mA intensity, and after 30 seconds the stimulation stops and the device turns off without informing the patient. The conventional treatment is also provided to the patient simultaneously for 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Aliakbar Dashtelei

Street address

Satar Khan, Niayesh Street, Hazrat Rasoul Akram Medical Education Complex

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rasoolhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza khatoonabadi

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khatoonabadi@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Aliakbar Dashtelei

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
To prevent plagiarism from the study data
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
Data on primary and secondary consequences is shared after coding.
When the data will become available and for how long
Access to data is possible two months after the publication of the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Just by mentioning the source of data and to refer to the literature.
From where data/document is obtainable
Deputy of Research, Rehabilitation Faculty, Tehran University of Medical Sciences
What processes are involved for a request to access data/document
Submitting a request to the Faculty Library and then obtaining the consent of Deputy of Research, Rehabilitation Faculty, Tehran University of Medical Sciences
Comments