

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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 second, 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)

##### Phone

+98 21 4680 4956

##### Email address

dashteleia@razi.tums.ac.ir

##### 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

###### **City**

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###### **Postal code**

1445613131

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+98 21 2501 5015

###### **Email**

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

###### **Street address**

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###### **Email**

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

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Aliakbar Dashtelei  
**Position**  
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**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
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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