

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating the Effect of Transcranial Electric Stimulation on Hand Tremor in Parkinson's Patients

#### Protocol summary

##### Study aim

Investigating the effect of cerebellar transcranial electric stimulation on the hand tremor in Parkinson's patients in two groups of intervention and sham.

##### Design

Clinical trials with intervention and sham group with single group, one blind, randomized clinical trial.

##### Settings and conduct

The study place is Firoozgar Hospital in Tehran. In the field of rehabilitation and improvement of Parkinson's patients. In an electrical stimulation session, a current of 2 mA was applied to the cerebellum for 15 minutes. The participant is blinded by which group (sham, intervention) participates.

##### Participants/Inclusion and exclusion criteria

Parkinson's patients should be a predominant tremor. Could not be withdrawn from antiparkinsonian drugs for 8 hours. There is no implant, rubbing or any metal object in the patient's body. No History of seizure and epilepsy. They don't have other neuropsychiatric diseases. They weren't being treated with deep brain stimulation.

##### Intervention groups

In the intervention group, the 2 mA electric current is applied to the cerebellum by an active electrode for 15 minutes, and in the sham group, the electric current of 2 mA in 30 seconds is applied and then stopped.

##### Main outcome variables

The amplitude of acceleration; Frequency of acceleration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190306042945N2**

Registration date: **2019-04-24, 1398/02/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-24, 1398/02/04**

Update count: **0**

##### Registration date

2019-04-24, 1398/02/04

##### Registrant information

###### Name

Bijan Forogh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8214 1612

###### Email address

forogh.b@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Effect of Transcranial Electric Stimulation on Hand Tremor in Parkinson's Patients

##### Public title

Effect of Non-invasive Electric Stimulation on Hand Tremor in Parkinson's Patients

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Parkinson's patients should be a predominant tremor. Could not be withdrawn from antiparkinsonian drugs for 8 hours.

**Exclusion criteria:**

There is implant, rubbing or any metal object in the patient's body. History of seizure and epilepsy. They have other neuropsychiatric diseases. They were being treated with deep brain stimulation

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **38**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization has been used.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participant is blinded by which group (sham, intervention) participates. In sham, only the first 30 seconds the electric current is applied to give emotions and signs of current, and after 30 seconds the current flow stops.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Iran University of Medical Sciences

**Street address**

Next to the Milad tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-02-24, 1397/12/05

**Ethics committee reference number**

IR.IUMS.REC.1397.1349

**Health conditions studied**

**1**

**Description of health condition studied**

Parkinson's disease

**ICD-10 code**

G20

**ICD-10 code description**

Parkinson's disease

**Primary outcomes**

**1**

**Description**

Amplitude of acceleration of the hand

**Timepoint**

Measure the acceleration of the hand before and after the intervention

**Method of measurement**

Accelerometer has LIS3DH sensor

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: To this group a cerebellum transcranial alternating electric stimulation with a current intensity of 2 mA and the peak frequency of each person in 15 minutes applied in a session.

**Category**

Rehabilitation

**2**

**Description**

Control group: For sham stimulation, sponge electrodes were applied in the same manner. The session times is 15 minutes, with only ramp running in about 30 seconds.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Soraya Rahimi

**Street address**

Maziar Mansouri Ave., Sattarkhan St.

**City**

Tehran

**Province**

Tehran  
**Postal code**  
1445613131  
**Phone**  
+98 21 6651 5001  
**Email**  
research@iums.ac.ir  
**Web page address**  
<http://hrmc.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Seyyed Kazam Malakouti  
**Street address**  
Tehran, Hemat Highway next to Milad Tower, Iran  
University of Medical Sciences  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Phone**  
+98 21 8670 2503  
**Email**  
research@iums.ac.ir  
**Web page address**  
<http://vcr.iums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Bijan Forogh  
**Position**  
Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Physical Medicine

#### Street address

Firoozgar Hospital, Behafarin Avenue, 1617763141,  
Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8214 1612

#### Fax

#### Email

forogh.b@iums.ac.ir

#### Web page address

<http://firoozgar.iums.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Bijan Forogh

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Physical Medicine

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#### Email

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## Person responsible for updating data

#### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Bijan Forogh

#### Position

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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**

No - There is not 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**

Information on the main outcome can be shared.

**When the data will become available and for how long**

The beginning of the access period is one year after the publication of the results in valid journals.

**To whom data/document is available**

Students

**Under which criteria data/document could be used**

To use data, the name of the data collector group should be mentioned in their study. The purpose and application of the data are explained in their study.

**From where data/document is obtainable**

By sending an email to "forogh.b@iums.ac.ir";  
"soraya.rahimi@aut.ac.ir"

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

The request is checked in the group.

**Comments**