

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of skin mechanoreceptors stimulation on resting tremor in parkinsonian patients and kinetic tremor in patients with essential tremor.

#### Protocol summary

##### Study aim

Investigation the effect of skin mechanoreceptor stimulation on rest tremor of parkinsonian patients and kinetic tremor of Essential tremor patients

##### Design

Clinical trial with three parallel, groups and blinded intervention, outcome assessment and analysis, designed of 15 patients.

##### Settings and conduct

Parkinson' patients will be study for 10 sessions (at neurologist' office). Two intervention groups and one control group reevaluate first session and final session and one month later by neurology resident ( based on UPDRS criteria, The Unified Parkinson's Disease Rating Scale) for Parkinsonian patient and TETRAS scoring for Essential tremor patients and these session acceleration of tremor will be recorded by biomedical PHD student. The data will be extracted with unknown identification for analysis.

##### Participants/Inclusion and exclusion criteria

Parkinson patients ( base on MDS criteria) that have rest tremor and collaboration ability , don't use DBS (deep brain stimulation) or Apomorphine pump. Essential tremor ( kinetic tremor of hand)

##### Intervention groups

First group parkinsonian patients is intervened by mechanical stimulation while the hand is rest position and second group , Essential tremor patients, while is drawing a figure. We put equipment just on the hand with out stimulation in control group

##### Main outcome variables

Tremor severity based on UPDRS criteria(The Unified Parkinson's Disease Rating Scale) for parkinsonian patients and TETRAS scoring for Essential tremor patients maximum of acceleration

#### General information

##### Reason for update

for assessment of skin mechanoreceptors stimulation on kinetic tremor, one group of Essential tremor is added.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210504051178N1**  
Registration date: **2022-02-05, 1400/11/16**  
Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-19, 1401/12/28**

Update count: **1**

##### Registration date

2022-02-05, 1400/11/16

##### Registrant information

###### Name

Seyede Pourandokht Mousavian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3502 3625

###### Email address

mousavianp981@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-05, 1400/11/16

##### Expected recruitment end date

2022-05-20, 1401/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Effect of skin mechanoreceptors stimulation on resting tremor in parkinsonian patients and kinetic tremor in patients with essential tremor.

**Public title**  
Effect of mechanical stimulation on parkinsonian tremor and Essential tremor

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Parkinson disease is diagnosed based on MDS criteria At least one hand has rest tremor 40 years old at the onset of disease. All patients will fill out a consent form Kinetic tremor in hand ( Essential tremor)

**Exclusion criteria:**

Severe disabilities Neuropathy MMSE score less than 26 Mood disorders and anxiety treatment with DBS and apomorphine pump Dose of drugs changed one month before Accompany of disorders or drugs that exaggerated tremor

**Age**  
From **40 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **15**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

Parkinson 'patients are selected , examined and grouped randomized by neurology resident. Intervention of each group is doing by biomedical engineering phd student. Neurology resident does examination of groups and gathers information but intervention of groups is unknown. Analysis of data is doing by phd student while the identity of data is not evident.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of mashhad university of medical sciences

**Street address**

No 11. Goldis Ave, Boronsi Blvd, mashhad city

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9179833367

**Approval date**

2021-01-19, 1399/10/30

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1399.775

## Health conditions studied

### 1

**Description of health condition studied**

Parkinson's disease

**ICD-10 code**

G20

**ICD-10 code description**

Parkinson's disease

### 2

**Description of health condition studied**

Essential tremor

**ICD-10 code**

G25.0

**ICD-10 code description**

Essential tremor

## Primary outcomes

### 1

**Description**

tremor severity

**Timepoint**

before beginning of intervention ( at the first of sampling and start of intervention), final session, after one month

**Method of measurement**

part 3 of UDPRS criteria (The Unified Parkinson's Disease Rating Scale) and accelerometer, TETRAS scoring for Essential tremor

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group 1: 5 parkinson' patients will be intervened on the hand while it is at a rest position , consecutive 10 session for half an hour duration is designed. Tremor severity will be evaluate based on UDPRS criteria and accelerometer at first and final session and one month later.

### Category

Treatment - Devices

## 2

### Description

Intervention group 2: 5 Essential tremor' patients will be intervened on the hand while it is drawing a figure , consecutive 10 session for half an hour duration is designed. Tremor severity will be evaluate based on TETRAS criteria and accelerometer at first and final session and one month later.

### Category

Treatment - Devices

## 3

### Description

Control group: We put equipment on the hand of 5 parkinson' patients at a rest position, consecutive 10 session for half an hour duration is designed. Tremor severity will be evaluate based on UDPRS criteria and accelerometer at first and final session and one month later.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Ali Shoeibi' office (MD)

#### Full name of responsible person

Ali Shoeibi

#### Street address

No 5, Daneshgah Ave, Mashhad city

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

0859306968

#### Phone

+98 51 3858 6858

#### Email

shoeibia@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran National Science Foundation

#### Full name of responsible person

Hamidreza Kobravi

#### Street address

Yousefi Ave, Emamieh Blvd, Islamic Azad University of Mashhad

#### City

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#### Province

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9187147578

#### Phone

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#### Email

hkobravi@mshdiau.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Iran National Science Foundation

### 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Ali Shoeibi

#### Position

Assistant Professor of neurology

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Neurology

#### Street address

Ghaem Hospital

#### City

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#### Province

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9187145785

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#### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ali Shoeibi

**Position**

Assistant Professor of neurology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neurology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyede Pourandokht Mousavian

**Position**

Neurology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

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**City**

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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**

some part of data can be communalized

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

6 months after publication

**To whom data/document is available**

researchers of scientific institution and university

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

different analysis for researchers

**From where data/document is obtainable**

Ali Shoeibi MD, Ahmad Abad Blvd, Qaem hospital,

shoeibia@mums.ac.ir

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

emailing, duration:3 weeks

**Comments**