

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 stimulationon 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)

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran National Science Foundation

Full name of responsible person

Hamidreza Kobravi

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Yousefi Ave, Emamieh Blvd, Islamic Azad University of Mashhad

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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

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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

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