Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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

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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 mechanichal 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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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran National Science Foundation

Full name of responsible person
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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
Neurology

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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