Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Non-invasive Median and Radial Nerve Stimulation in tremor alleviating in Patients with Action Tremor: A double-arm, randomized, double-blind clinical trial (Device Clinical Test)

Protocol summary

Study aim

Investigating the effect of peripheral stimulation of median and radial nerves on amplitude and frequency of active tremor of the hand after 40 minutes of electrical stimulation

Design

A two-arm, double-blind, sham-controlled clinical trial with an 84-samplesize, Block randomized by https://www.sealedenvelope.com/simple-randomiser/v1/lists, website.

Settings and conduct

The patient receives electrical or artificial stimulation by a wristband device; Study participants, outcome assessors, and data analysts are blinded. Neurology clinic, Iranian Center of Neurological Research, Imam Khomeini Hospital, Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Participants: patients with active hand tremor / Inclusion Criteria: over 18 years old, confirmation of active tremors by a neurologist, if taking medication for tremor dose and type of medication from one month before the start of this study and during the study. Exclusion Criteria: advanced liver and kidney disease, patient with medical electrical equipment in the body such as: pacemaker, defibrillator, deep brain stimulation, history of thalamotomy, epilepsy disorders, peripheral neuropathy, severe dependence on alcohol or caffeine, platinum in the forearm , pregnancy, use of botulinum treatment for hand tremor in the past six months, other neurodegenerative diseases, change of medication or addition of a new medication from one month before or during the study

Intervention groups

Intervention group: Electrical stimulation by a wristband device of two median and radial nerves with a frequency of 150 Hz Control group: Sham-stimulation with a frequency of 7 Hz by wristband device

Main outcome variables

The Essential Tremor Rating Assessment (TETRAS); BF-activities of daily living (BF-ADL) ; Clinical global impressions (CGI-I); Tremor power

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161212031362N2**
Registration date: **2022-09-12, 1401/06/21**
Registration timing: **prospective**

Last update: **2022-09-12, 1401/06/21**
Update count: **0**

Registration date

2022-09-12, 1401/06/21

Registrant information

Name

Mohammad Hossein Harirchian

Name of organization / entity

Iranian center of neurological research

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 8899

Email address

harirchm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Non-invasive Median and Radial Nerve Stimulation in tremor alleviating in Patients with Action Tremor: A double-arm, randomized, double-blind clinical trial (Device Clinical Test)

Public title

Evaluation of Non-invasive Peripheral Nerve Stimulation in Action Tremor (Device Clinical Test)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Action Tremor

Exclusion criteria:

Advanced liver disease Advanced renal disease Patients with Implemented electrical medical device such as: pacemaker, defibrillator, Deep brain stimulation A history of thalotomy Epileptic disorders Peripheral neuropathy Severe addiction to alcohol or caffeine Platinum in forearm Skin sores at the site of stimulation Pregnancy Receive botulinum treatment for hand tremors during the past six months Any neurodegenerative diseases Changing the medication or adding a new medication one month before

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block (Ṡample Size: 84 (21 Blocks) Randomization Unit: Individual Random sequence by Rand Excel; Website: https://www.sealedenvelope.com/simple-randomiser/v1/lists

Blinding (investigator's opinion)

Double blinded

Blinding description

The wristband device is designed with the ability to adjust the electrical stimulation and artificial stimulation, which are named A and B by the researcher. Study participants, outcome assessors, and data analysts are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Neuroscience Institute , Tehran University of Medical Sciences

Street address

Neuroscience Institute, Imam Khomeini Hospital complex; Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2022-08-04, 1401/05/13

Ethics committee reference number

IR.TUMS.NI.REC.1401.039

Health conditions studied

1

Description of health condition studied

Patients with Action Tremor

ICD-10 code

G25.0

ICD-10 code description

Essential tremor

Primary outcomes

1

Description

The Essential Tremor Rating Assessment (TETRAS) scale-6 task Archimedes score

Timepoint

Before electrical stimulation, 15 minutes after stimulation, then at intervals of 30 minutes, 60 minutes, 90 minutes, 120 minutes after electrical stimulation.

Method of measurement

The Essential Tremor Rating Assessment (TETRAS) and score calculation

2

Description

Bain and Findley activities of daily living (BF-ADL) test

score

Timepoint

Before electrical stimulation, 15 minutes after stimulation, then at intervals of 30 minutes, 60 minutes, 90 minutes, 120 minutes after electrical stimulation.

Method of measurement

Bain and Findley activities of daily living (BF-ADL) questionnaire and score calculation

3

Description

Patient's report of improvement by Clinical global impressions (CGI-I) questionnaire

Timepoint

Before electrical stimulation, 15 minutes after stimulation, then at intervals of 30 minutes, 60 minutes, 90 minutes, 120 minutes after electrical stimulation.

Method of measurement

Clinical global impressions questionnaire and score calculation

4

Description

Tremor power (Frequency)

Timepoint

Before electrical stimulation, 15 minutes after stimulation, then at intervals of 30 minutes, 60 minutes, 90 minutes, 120 minutes after electrical stimulation.

Method of measurement

Electrical Stimulation Wristband device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Electrical stimulation of two median and radial nerves with a frequency of 150 Hz, by a wristband device

Category

Treatment - Devices

2

Description

Control group: Sham-stimulation of two median and radial nerves with a frequency of 7 Hz, for 15 seconds by a wristband device

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Center of Neurological Research

Full name of responsible person

Mohammad Hossein Harirchian

Street address

Iranian Center of Neurological Research, Imam Khomeini Hospital Complex, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6694 8899

Email

harirchm@tums.ac.ir

Web page address

https://isid.research.ac.ir/MohammadHosein_Harirchian

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbar Fotouhi

Street address

Keshavarz Blvd, Qods Town.

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۵۳۷۶۱

Phone

+98 21 81631

Email

tumspr@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
Mohammad Hossein Harirchian

Position
Professor of Neurology

Latest degree
Specialist

Other areas of specialty/work
Neurology

Street address
Iranian Center of Neurological Research, Imam Khomeini Hospital, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6694 8899

Fax
+98 21 6658 1558

Email
harirchm@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Hossein Harirchian

Position
Professor of Neurology

Latest degree
Specialist

Other areas of specialty/work
Neurology

Street address
Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6694 8899

Fax
+98 21 6658 1558

Email
harirchm@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Hossein Harirchian

Position
Professor of Neurology

Latest degree
Specialist

Other areas of specialty/work
Neurology

Street address
Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6694 8899

Fax
+98 21 6658 1558

Email
harirchm@tums.ac.ir

Web page address
https://isid.research.ac.ir/MohammadHosein_Harirchian

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available