Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Determining and Predicting the Effect of Mechanical Perturbation Therapy on the Neuromuscular Responses of Ankle in Stroke Patients Using Parameter Varying System Identification Method

Protocol summary

Study aim
Determining and predicting the therapeutic effect of therapeutic mechanical vibrations on the neuromuscular characteristics of the ankle joint in stroke patients using the parameter varying system identification method.

Design
The study has an intervention and control group with 10 members each that were selected randomly between the patients referred to the rehabilitation center who met the criteria for entering the study using the Rand function.

Settings and conduct
To record data, a robotic rehabilitation device is used to control the position of the ankle. The coordinates of the joint position are recorded using a precise sensor. The torque is recorded using a torque cell with 6 degree of freedom. The ankle must be put in the pedal of the machine so that the axis of the torque is aligned with the axis of the ankle, then perturbations is applied to the ankle by the device. During the training, the patient is asked to resist the movement of their ankle by the motor to detect and record voluntary movement. The ankle should be relaxed during the measurement and active during the train.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Spasticity and unilateral movement disorder caused by stroke in the ankle, No cognitive impairment or aphasia, Not having a history of previous strokes and epilepsy Exclusion Criteria: Existence of pacemaker implants or metal implants in the skull and face, Usage of drugs to increase or decrease motor excitability, Absence of abnormality or fraction in the skull, Absence of osteoporosis.

Intervention groups
Intervention group:10 patients that meet the inclusion criteria will take robotic rehabilitation. Control group:10 patients that meet the inclusion criteria will take conventional rehabilitation treatment without robot intervention.

Main outcome variables
Reduction of the Stiffness & Increase of Range of Motion After Rehabilitation Period

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220913055959N1**
Registration date: **2022-10-27, 1401/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-27, 1401/08/05**
Update count: **0**

Registration date
2022-10-27, 1401/08/05

Registrant information
Name
Elham Sadeghi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining and Predicting the Effect of Mechanical Perturbation Therapy on the Neuromuscular Responses of Ankle in Stroke Patients Using Parameter Varying System Identification Method

Public title

Investigating the Effect of the Robot in Treatment of Neuromuscular Disorders in Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Movement Disorder in Ankle Due to Stroke

Exclusion criteria:

Osteoporosis and Having Implants in the Head and Feet

Age

From **5 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

This study had been used block randomization. According to the sample size (20 patients), 10 blocks including 2 cells each, had been prepared with two formats of A-B and B-A according to the following procedure. Position A belongs to the control group and position B belongs to the intervention group. These blocks had been assigned digits from 1 to 10. One digit had been generated randomly using the Rand function in MATLAB. If the output digit was between 1 to 6, the A-B position should be assigned, if the output digit was between 7 to 10, the B-A position should be assigned. The first cell of the first block would be assigned to the first patient. The second cell of the first block would be assigned to the second patient and this assignment procedure should be done till the last patient from the rest blocks respectively, so every patient had been taken position A or B.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commottee of Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Science, Qods Ave.,Keshavarz Blvd.

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Tehran

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Postal code

1417653761

Approval date

2022-08-11, 1401/05/20

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.300

Health conditions studied

1

Description of health condition studied

Movement disorders caused by neuromuscular damage due to stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stiffness of Ankle, Range of Motion of Ankle

Timepoint

Before and After the Robotic Rehabilitation

Method of measurement

Robotic Device of Rehabilitation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients of this group will be rehabilitated by the robotic device for 1 month and 3 days a week. Rehabilitation exercises will apply by a robotic device with a software setting specialized for each patient. During the training sessions, the patient will be asked to resist the movement applied to the

ankle. The used robotic device in this study is a prototype of a registered patent by Dr. Mohammad Mehdi Mirbagheri who obtained a clinical certificate from the General Directorate of Medical Equipment and Devices of the Iran Food and Drug Administration.

Category

Rehabilitation

2

Description

Control group: Patients of this group will be treated by conventional physiotherapy without the robotic device. The patients will be evaluated by the robotic device. Improvement of neuromuscular parameters will be analyzed and compared with the Intervention group

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fakhr e Sadegh rehabilitation center

Full name of responsible person

Mohamad Mehdi Mirbagheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

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

Mohamad Mehdi Mirbagheri

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Technical data of patient is not suitable for publication
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable