

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Studying the clinical and electrophysiological mechanisms of the short term effects of local plantar vibration on balance in patients with chronic stroke(pilot study)

Protocol summary

Study aim

Explanation of the possible effects of local vibration of the soles of the feet on different systems affecting balance

Design

Before and after intervention study, one intervention group, 12 patients, sample size with non-parametric Wilcoxon test

Settings and conduct

first session Patients visit the clinic and fill in the consent form and information questionnaire, balance assessment by mini-best test, assessment of spasticity (MMAS) and plantar surface sensation (SWMF) and range of ankle dorsiflexion, recording of Hoffman's reflex, application of vibration for 5 minutes with 100 Hz frequency, 3 middle sessions of vibration application based on the patient's choice, it is done in the form of a home visit at home or a visit to the clinic in person, the last session (fifth) visit the clinic in person and apply vibration and repeat all the evaluations of the first session

Participants/Inclusion and exclusion criteria

Criteria for entering the study: ● Diagnosis of stroke by a neurologist ● At least 3 months have passed since the last stroke ● Suffering from stroke-induced balance disorder based on the one-leg standing test (the patient's inability to stand on the more involved leg for 30 seconds with eyes open) Criteria for not entering the study: People who were undergoing other treatments to improve balance The presence of any other neurological disease, other than stroke, that leads to balance deficits (such as Parkinson's and cerebellar injuries, etc.)

Intervention groups

The local vibration of the soles of the feet with a frequency of 100 was applied for 5 minutes and in 5 sessions every other day

Main outcome variables

Hmax/Mmax Hmax latency Minibest test score Severity

of spasticity dorsiflexion ROM sense of plantar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221116056517N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **retrospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

mahsa dastkhosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6534 5080

Email address

mahsadastkhosh75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-16, 1401/08/25

Expected recruitment end date

2022-12-14, 1401/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the clinical and electrophysiological mechanisms of the short term effects of local plantar vibration on balance in patients with chronic stroke(pilot study)

Public title

Studying the clinical and electrophysiological mechanisms of the short term effects of local plantar vibration on balance in patients with chronic stroke(pilot study)

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of stroke by a neurologist At least 3 months have passed since the last stroke Suffering from stroke-induced balance disorder based on the one-leg standing test (inability of the patient to stand on the more involved leg for 30 seconds with eyes open) Ability to stand and walk independently Ability to understand and follow instructions A person's body mass index should not be above the limit of 30

Exclusion criteria:

People who were undergoing other treatments to improve balance The presence of any other neurological disease, other than stroke, that leads to balance deficits (such as Parkinson's and cerebellar injuries, etc.) Lower extremity surgery within the past year Severe visual impairment (hemi anopia) and impairment of the vestibular-auditory system

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 12

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

No. 33 , West sajedin Alley., Ebnesina Ave., Dr Hesabi Ave., Phase5., Andisheh Town

City

Tehran

Province

Tehran

Postal code

1481946491

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

62033

Health conditions studied**1****Description of health condition studied**

Chronic Brain Stroke

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hmax/Mmax

Timepoint

The beginning of the study (before the start of the intervention) and the end of the study (after 5 intervention sessions)

Method of measurement

Electromyography

Secondary outcomes**1****Description**

Balance

Timepoint

The beginning of the study (before the start of the intervention) and the end of the study (after 5 intervention sessions)

Method of measurement

Minibest Test

Intervention groups

1

Description

Intervention group: local vibration of the soles of the feet with a frequency of 100 Hz for 5 minutes and in 5 sessions every other day is applied to both soles of the patient.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک کاردرمانی لیام

Full name of responsible person

Mohaddeseh Gorji

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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

50

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

Sofia Naghdi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Other areas of specialty/work

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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