Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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 scienece

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
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Physiotherapy

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Person responsible for updating data

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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