Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

A clinical study to investigate the immediate effects of plantar vibration on balance in patients after stroke

Protocol summary

Summary

The present study aimed to investigate the immediate effects of plantar vibrationon balance in patients after stroke. The patients were recruited from neurological rehabilitation clinics of Tehran and Iran University of Medical Sciences. The inclusion criteria were patients with spastic hemiplegia who were able to stand and walk independently. Patients were excluded if they were taking anti-spastisity drugs.The patients were referred to neurological physiotherapy clinic, school of rehabilitation, Tehran University of Medical Sciences for vibration therapy. There was one group of subjects with stroke which received 2 interventions with one week interval. Twenty patients underwent treatment with active vibration (frequency 100 Hz, 5 minutes, single session) 7 days after placebo vibration (5 minutes while the device was off, single session). The primary outcome measure, balance control based on mini-BESTest: and the secondary outcome measures, spasticity intensity based on MMAS and passive range of motion; were assessed before and after placebo vibration as well as active vibration, applied to the more affected foot.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102230430N1**
Registration date: **2016-11-18, 1395/08/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-11-18, 1395/08/28

Registrant information

Name

Soofia Naghdi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 5132

Email address

naghdi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical study to investigate the immediate effects of plantar vibration on balance in patients after stroke

Public title

Effects of plantar vibration therapy on balance after stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hemiplegia after stroke; Spasticity intensity of affected ankle plantar flexors based on Modified Modified Ashworth Scale(MMAS)>=1; independent standing and walking; Ability to follow instructions. Exclusion criteria: Taking anti-spastisity

drugs; unwillingness to continue the study.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Other

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
Department of Physiotherapy, School of Rehabilitation, Pitch-e-Shemiran, Enghelab Avenue.

City
Tehran

Postal code

Approval date
2016-03-06, 1394/12/16

Ethics committee reference number
IR.TUMS.REC.1394.2152

Health conditions studied

1

Description of health condition studied
Stroke

ICD-10 code
I69.4

ICD-10 code description
Sequelae of stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Balance

Timepoint
Before and immediately after plantar vibration and placebo vibration

Method of measurement
Calculating mini BESTest Score

Secondary outcomes

1

Description
Spasticity

Timepoint
Before and immediately after plantar vibration and placebo vibration.

Method of measurement
Based on Modified Modified Ashworth Scale(MMAS) scores

2

Description
Passive Range of Motion

Timepoint
Before and immediately after plantar vibration and placebo vibration.

Method of measurement
Goniometry

Intervention groups

1

Description
Intervention 1: plantar vibration. Vibration stimuli with a frequency of 100 Hz was applied for 5 minutes to the sole of more affected foot for one session.

Category
Rehabilitation

2

Description
Intervention 2: Placebo vibration. The affected foot was placed on the vibrator plate for 5 minutes while the device was off, for one session.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurological physiotherapy clinic, School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Azam Karimi Ahmadabadi

Street address

Neurological physiotherapy clinic, School of Rehabilitation, Pitch-e-Shemiran, Enghelab Avenue.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Soofia Naghdi

Street address

Department of Physiotherapy, School of Rehabilitation, Pitch-e-Shemiran, Enghelab Avenue.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation,Tehran University of Medical Sciences

Full name of responsible person

Dr. Soofia Naghdi

Position

Associate Professor, Physiotherapy Department of School of Rehabilitation

Other areas of specialty/work

Street address

Department of Physiotherapy, School of Rehabilitation, Pitch-e-Shemiran, Enghelab Avenue.

City

Tehran

Postal code

Phone

+98 21 7753 5132

Fax

Email

naghdi@tums.ac.ir; nakhostin@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation,Tehran University of Medical Sciences

Full name of responsible person

Dr. Soofia Naghdi

Position

PhD of Physiotherapy

Other areas of specialty/work

Street address

Department of Physiotherapy, School of Rehabilitation, Pitch-e-Shemiran, Enghelab Avenue.

City

Tehran

Postal code

Phone

+98 21 7753 5132

Fax

Email

naghdi@tums.ac.ir; nakhostin@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Physiotherapy, School of Rehabilitation,Tehran University of Medical Sciences

Full name of responsible person

Dr. Soofia Naghdi

Position

Associate Professor, Physiotherapy Department of School of Rehabilitation

Other areas of specialty/work

Street address

Department of Physiotherapy, School of Rehabilitation, Pitch-e-Shemiran, Enghelab Avenue.

City

Tehran

Postal code

Phone

+98 21 7753 5132

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty