# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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*