

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of somatosensory stimulation through a vibratory orthosis on balance control in hemiparetic stroke patients

#### Protocol summary

##### Summary

1)Objective: to evaluate the effect of applying vibratory belt on improving static and dynamic balance in CVA hemiparetic patients 2)Design: Body imbalance is a common problem in hemiparetic CVA patients. Impaired postural control could be an important complication of their illness. It can increase the risk of falling and fractures during and after rehabilitation phase in this population. A new modality which can possibly help to improve balance in these patients is somatosensory stimulation. There is few clinical trials to date which evaluate vibration as a somatosensory stimulation especially focal vibration instead of whole body vibration to improve balance. Vibrational somatosensory stimulation in Parkinson disease was shown to improve balance control.in this cross-over clinical trial we are going to design a vibratory belt and assesse the locally used vibration effect (phase 2)on 20 hemiparetic post CVA patients referred to the Firoozgar hospital physical medicine and rehabilitation center(single center), by using Biodex balance system static and dynamic tests. Due to vibratory cue during the test, this study will not be blind neither for the participants nor the person who accomplishes the tests and gathers the data. 3)Setting and conduct: four different positions(static/dynamic and open/closed eye) while applying lumbar belt with Vibration ON/OFF, will evaluate separately in one session for each patient by overall stability index measured with Biodex balance system. Before applying the belt the patient's balance will be tested, and will compare with the test result during applying the belt. Biodex balance system include tow balance platforms (soft and hard) with 12 different degrees of stability from easy to difficult. The system also contains a monitor in front of the patient to accomplish the selected balance test according the visual clues shown in the monitor. 4) Inclusion criteria are: post stroke hemiparesia; at least one month passed after stroke episode; patients must experience only one stroke attack; be able to maintain

independent unsupported stance for at least 30 seconds. Exclusion criteria are: patients who had orthopaedic impairment with significant impact on standing balance; severe spasticity interfere with standing balance; cerebellar or brain stem induced balance impairment; history of vestibular balance impairment or severe peripheral neuropathy and cardiac pace maker. 5)Intervention in this study is applying the vibratory belt during the static and dynamic balance tests (which will be done with Biodex balance system) 6)Primary outcome measure: over all stability index (OSI) in 4 different positions (static/dynamic and open/closed eye) before applying the vibratory belt. Secondary outcome measure: over all stability index (OSI) in 4 different positions (static/dynamic and open/closed eye) during applying the vibratory belt.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012122611890N1**

Registration date: **2017-02-25, 1395/12/07**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-25, 1395/12/07

##### Registrant information

##### Name

Arash Majdzadeh

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8214 1229

##### Email address

**Recruitment status**

Recruitment complete

**Funding source**

Iran University of Medical Sciences

**Expected recruitment start date**

2016-05-01, 1395/02/12

**Expected recruitment end date**

2017-03-15, 1395/12/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of somatosensory stimulation through a vibratory orthosis on balance control in hemiparetic stroke patients

**Public title**

Effect of vibratory orthosis on balance control in hemiparetic stroke patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: post stroke hemiparesia; at least one month passed after stroke episode; patients must experience only one stroke attack; be able to maintain independent unsupported stance for at least 30 seconds. Exclusion criteria: patients who had orthopedic impairment with significant impact on standing balance; severe spasticity interfere with standing balance; cerebellar or brain stem induced balance impairment; history of vestibular balance impairment or severe peripheral neuropathy and cardiac pace maker.

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: **18**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics commity of Tehran University of Medical Science

**Street address**

Firoozgar hospital, Beh-Afarin alley, Valiye-Asr square, Tehran

**City**

tehran

**Postal code**

**Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

130/2965/91/3

**Health conditions studied**

**1**

**Description of health condition studied**

Stroke

**ICD-10 code**

I69.4

**ICD-10 code description**

Stroke, not specified as haemorrhage or infarction

**Primary outcomes**

**1**

**Description**

overall stability index with vibratory belt OFF in static and dynamic, open/closed eye positions

**Timepoint**

once, just before testing the patients with vibratory belt ON

**Method of measurement**

Biodex balance system

**Secondary outcomes**

**1**

**Description**

overall stability index with vibratory belt ON in static and dynamic, open/closed eye positions

**Timepoint**

immediately after testing the patients with vibratory belt OFF.

**Method of measurement**

Biodex balance system

## Intervention groups

### 1

#### Description

control group receive the same belt with motors OFF during static and dynamic balance testing of Biodex balance system.

#### Category

Rehabilitation

### 2

#### Description

providing vibration through electrical motors in the belt in intervention group during static and dynamic balance testing with Biodex balance system.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Firoozgar hospital

##### Full name of responsible person

Dr arash majdzadeh

##### Street address

Firoozgar hospital, Beh-Afarin alley, Valiye-Asr square, Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor For Research Of Iran University of Medical Science

##### Full name of responsible person

Dr arash majdzadeh

##### Street address

Medical faculty, Iran University of Medical Science, Hemmat High way, Tehran

##### 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 Iran University of Medical Science

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Arash Majdzadeh

##### Position

MD, resident of physical medicine

##### Other areas of specialty/work

##### Street address

Medical faculty, Iran University of Medical Science, Hemmat High way, Tehran

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##### Postal code

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+98 21 4423 4918

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Dr. Bijan Forogh

##### Position

professor

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Arash Majdzadeh

**Position**

MD

**Other areas of specialty/work****Street address**

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**City**

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**Postal code****Phone**

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**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*