

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

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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

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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

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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