Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity

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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/د

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 majdzdaeh
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
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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
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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