

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of hip joint mobilization with movement on muscle activity pattern, postural control and static and dynamic balance in patients with chronic stroke: Randomized clinical trial

Protocol summary

Study aim

-Determining the pattern of muscle activity, postural stability, dynamic and functional balance before, after and two weeks after treatment in each group and between groups

Design

This clinical trial contains: a control group, parallel group trial, double blinded, pilot study, permuted block randomization with a block size of 4

Settings and conduct

After screening, the patients with hemiplegia following stroke will sign the informed consent. The patients will be randomly allocated to the experimental (hip joint mobilization with movement) and the control group (conventional physiotherapy). Assessments and statistical analysis will be performed by blinded physiotherapist and statistician, respectively.

Participants/Inclusion and exclusion criteria

-Hemiplegia secondary to stroke; -stroke onset >6 months; -The ability to stand and walk independently; Exclusion criteria: -Any orthopedic and neurological disease affecting balance control; -Contraindications for hip joint mobilization and superficial electromyography;

Intervention groups

Intervention group: hip joint mobilization with movement in addition to the conventional physiotherapy Control group: conventional physiotherapy

Main outcome variables

Postural stability; dynamic balance; functional balance and muscle activity pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200613047759N1**

Registration date: **2020-08-02, 1399/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-02, 1399/05/12**

Update count: **0**

Registration date

2020-08-02, 1399/05/12

Registrant information

Name

soudeh arabzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hip joint mobilization with movement on muscle activity pattern, postural control and static and dynamic balance in patients with chronic stroke: Randomized clinical trial

Public title

The effect of hip joint mobilization with movement on muscle activity, and balance in patients with chronic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

-The presence of hemiplegia secondary to stroke -History of stroke onset >6 months and a maximum of 1 year prior to the study -The ability to stand and walk independently without the use of assist-devices -Mini-Mental State Examination score of >24 -Within stages 2-4 of Brunnstrom -The age range of 35-65 years old -The ability to follow verbal commands

Exclusion criteria:

-Any orthopedic disease affecting balance control -Any neurological condition affecting balance control -Taking any medication that causes peripheral neuropathy -Have a visual impairment -Have a hearing impairment -Have a history of spinal disorders affecting gait and lower limb function -There is a cerebellar stroke at the same time - Contraindications for hip joint mobilization - Contraindications on the use of superficial electromyography

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with a block size of 4 will be done with statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of whether they are in the control or experimental group. Also all outcome will be measured and analyzed by an experienced physical therapist and statistician, who was blinded to the grouping. Also, in order to blind the participants, the treatment of each group will be done on different days of the week.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Second Floor, No. 18, Niloufar Alley, Hasht Behesht Sharghi St.

City

Isfahan

Province

Isfahan

Postal code

8157686811

Approval date

2020-06-09, 1399/03/20

Ethics committee reference number

IR.SUMS.REHAB.REC.1399.019

Health conditions studied

1

Description of health condition studied

Chronic stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postural stability

Timepoint

1 day before intervention, 1 day after intervention and 14 days after intervention

Method of measurement

Biodex balance system

2

Description

Dynamic balance

Timepoint

1 day before intervention, 1 day after intervention and 14 days after

Method of measurement

Time Up and Go test

3

Description

Functional balance

Timepoint

1 day before intervention, 1 day after intervention and 14 days after

Method of measurement

Berg Balance Scale

Secondary outcomes

1

Description

Muscle activity pattern

Timepoint

1 day before intervention, 1 day after intervention and 14 days after intervention

Method of measurement

Surface electromyography

Intervention groups

1

Description

Experimental group: hip joint mobilization with movement technique for three times per week for 4 weeks, a grade III glide will be sustained for 10 seconds and relaxed for 5 seconds over 3 sets of 6 repetitions with a 1- minute rest between sets after receiving 30 minutes of conventional physiotherapy

Category

Rehabilitation

2

Description

Control group: 30 minutes of conventional physical therapy, 3 times a week for 4 weeks as follows: the first 10 minutes of the active and passive range of motion exercises for the lower limb of the affected side; the next 10 min for Weigh Bearing training during sitting and standing; and the final 10 min for walking.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of School of Rehabilitation Sciences

Full name of responsible person

Mohsen Razeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Yunes Ghasemi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Soudeh Arabzadeh

Position

PhD candidate in physiotherapy

Latest degree

Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After coordination with the Research Ethics Committee for approval of the ethics committee, participants data file will be provided in complete secrecy and for research purposes only.

When the data will become available and for how long

After acceptance of the article by the journal

To whom data/document is available

In addition to the principal researcher and the supervisor of the project, upon request, access to information can be reviewed by the Ethics Committee.

Under which criteria data/document could be used

Preferably it is only used for the subject of my research, but if research is to be done in order to use the statistical population, the main project executor and the student's main collaborator will make a decision with the permission of the ethics committee.

From where data/document is obtainable

Executors of the project can first be referred to through Dr. Fahimeh Kamali Sarvestani (09177110341), secondly through Dr. Mohsen Razaghi (09173130718) and the main colleague and student collaborator Ms Soudeh Arabzadeh (09369332615).

What processes are involved for a request to access data/document

6 months after the article was published, referring the request to the executor of the project, in addition, an official letter from the ethics committee will be commented on in order to obtain a license, and if the ethics committee approves, emphasizing the confidentiality of the information, the requested information will be provided to the applicant.

Comments