

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A comparative study of the effect of reactive and proactive exercises on ankle spasticity in patients with stroke: a randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of reactive and proactive exercises on mean spasticity and functional outcomes among experimental and control groups.

Design

This study is a double blind clinical trial that is performed in parallel on three groups of 10 people: reactive, proactive and control exercises. Randomization of patients participating in this study is done based on a block chart by an uninformed person

Settings and conduct

The place of this study is the physiotherapy ward of Kashani Hospital in Isfahan. After obtaining an ethics license from the Medical Ethics Committee of Isfahan University of Medical Sciences and also registering the study protocol in the Iranian Clinical Trials Registration System, patients with stroke are referred by a neurologist or by advertising in private and public treatment centers under the supervision of the University. Isfahan Medical Sciences are invited to this study.

Participants/Inclusion and exclusion criteria

In this study, patients with stroke are diagnosed by a neurologist. One of the most important conditions for inclusion in the study of these patients is having spasticity in the ankle and mental conditions suitable for performing exercises. Patients should also be able to stand and walk without assistive devices. The most important conditions for exclusion are other neurological problems and pain in the lower extremity.

Intervention groups

In this study, patients are divided into three groups (two groups of reactive and proactive exercise intervention) and the control group. All patients receive conventional evidence-based treatment for stroke rehabilitation. The control group receives only conventional treatment and the two intervention groups receive special balance exercises (reactive and proactive) in addition to conventional treatment according to the type of group.

Main outcome variables

Muscle tone, H reflex latency, H max / M max ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200101045970N4**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Ehsan Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-10, 1399/07/19

Expected recruitment end date

2021-06-09, 1400/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of reactive and proactive exercises on ankle spasticity in patients with stroke: a randomized clinical trial

Public title

The effect of exercise therapy on ankle spasticity in patients with stroke

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A history of the first unilateral stroke confirmed by a neurologist through CT scan or MRI findings. At least 6 months have passed since the onset of stroke symptoms. Having spasticity in the gastrocnemius muscle based on the Modified Modified Ashworth Scale (MMAS \geq 1) Existence of appropriate cognitive status to understand simple verbal commands and following them based on the Persian version Mini-mental status examination \geq 24 Ability to stand and walk independently without an aid

Exclusion criteria:

Existence of other neurological disorders such as Parkinson's and Existence of severe visual, profound and vestibular disorders Existence of severe orthopedic disorders such as fixed contractures in the lower extremities Severe pain in the lower extremities: According to the VAS scale, pain between 75 and 100 mm Participate in other rehabilitation treatment interventions Taking medications that affect the degree of spasticity. Having a weight of more than 150 kg and a height of more than 2.1 meters

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method was used for random allocation. Using a statistical software, the statistician designed 10 blocks of 3, considering that we had 3 groups. The person who divides patients according to this table is unaware of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the study are unaware of treatment groups. The outcome assessor is also unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Hezar Jrib

City

Isfahan

Province

Isfahan

Postal code

817473461

Approval date

2020-09-06, 1399/06/16

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.302

Health conditions studied**1****Description of health condition studied**

stroke

ICD-10 code

G81

ICD-10 code description

Hemiplegia and hemiparesis

Primary outcomes**1****Description**

Muscle Tone

Timepoint

Before treatment, after treatment and two months follow-up

Method of measurement

Modified Modified Ashworth Scale

2**Description**

H reflex Latency

Timepoint

Before treatment, after treatment and two months follow-up

Method of measurement

Nerve electrical activity recorder

3

Description

H max / M max ratio

Timepoint

Before treatment, after treatment and two months follow-up

Method of measurement

Nerve electrical activity recorder

Secondary outcomes

1

Description

Functional Mobility

Timepoint

Before treatment, after treatment and two months follow-up

Method of measurement

Timed UP and Go test (TUG)

Intervention groups

1

Description

Intervention group: Reactive Exercises:1. Creating disturbance in sitting and standing position 2. Pushing and releasing 3. Standing on an unstable surface 4. Cowboy exercise

Category

Rehabilitation

2

Description

Intervention group: Proactive Exercises: 1. catch and throw the ball 2. spin 3. pull the hand forward 4. stand on one foot 5. stand and walk in a tandem position

Category

Rehabilitation

3

Description

Control group: Conventional physiotherapy, according to studies, includes range of motion exercises related to the upper and lower limbs, weight lifting on the affected side, walking in parallel load forward and backward, pelvic bridging exercises and stretching exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Isfahan Kashani Hospital

Full name of responsible person

Dr. Majid Ghasemi

Street address

Kashani

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Ehsan Ghasemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to misuse of information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol, informed consent form and clinical study report

When the data will become available and for how long

The study protocol and consent form are now available in the proposal. The clinical study report will be published after the work is completed.

To whom data/document is available

All researchers working in scientific institutes can access the proposal.

Under which criteria data/document could be used

To be aware of the study conditions and get acquainted with scientific concepts.

From where data/document is obtainable

Contact Dr. Ehsan Ghasemi via email or mobile.

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

Immediately after sending the email and receiving the request.

Comments