Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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≥1) Existence of appropriate cognitive status to understand simple verbal commands and following them based on the Persian version Mini-mental status examination ≥ 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 than2.1 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
Isfehan

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
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Sponsors / Funding sources

1

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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
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Assistant Professor
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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