

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of passive range of motion exercises on motor function of patients in acute phase of stroke: a clinical trial.

Protocol summary

Summary

The aim of this study is to examine the effect of passive range of motion exercise in the acute phase of stroke on motor function of the patients. In this randomized controlled trial, patients with stroke who are recruited based on inclusion criteria, are randomly allocated to experimental and control group using closed envelopes each of which includes a group name. Inclusion criteria would be ischemic stroke diagnosis, no longer than 6 hours of the stroke onset, score 14-16 based on FOUR criteria, NIHSS 5-42, Age 18-80 years old, Vital signs within normal range; and exclusion criteria would be past history of stroke, fracture or orthopedic disorder in extremities, acute coronary syndrome, heart and respiratory failure, life threatening condition, history of neurologic dysfunction, patients death, intervention sessions less than 6, activity intolerance, patient discharge before intervention termination, and clinical instability within the first 48 hours of intervention. In experimental group, passive range of motion for involved extremities will be implemented within the first 48 hours of strike onset by the researcher. Before intervention, and one month and three months after intervention termination, motor function of the experimental and control group will be measured by Muscle Strength Scale and the measurements will be compared by statistical tests. The person who measures dependent variable would be blind to the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020213785N4**

Registration date: **2017-03-02, 1395/12/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-02, 1395/12/12

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-09-11, 1393/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of passive range of motion exercises on motor function of patients in acute phase of stroke: a clinical trial.

Public title

Effect of passive range of motion exercises on motor function in stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ischemic stroke diagnosis, no longer than 6 hours of the stroke onset, score 14-16 based on FOUR criteria, NIHSS 5-42, Age 18-80 years old, Vital signs within normal range
Exclusion criteria: Past history of stroke; fracture or orthopedic disorder in extremities; acute coronary syndrome; heart and respiratory failure; life threatening condition; history of neurologic dysfunction

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

At the corner of Ghods St, Keshavarz Blvd

City

tehran

Postal code

Approval date

2013-07-14, 1392/04/23

Ethics committee reference number

647P

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Motor function

Timepoint

Before intervention, one month and three months after intervention termination

Method of measurement

Muscle Strength Scale

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: Passive range of motion exercises for involved extremities will be implemented within the first 48 hours of stroke onset by the researcher according to the protocol, four times daily, each time for 15-40 minutes. In case of patient's intolerance to the intervention and vital sign instability, the intervention would be stopped. Implementing at least 6 sessions of intervention is necessary. The intensity of the exercise will be moderate at the beginning and will be increased based on the patient's tolerance.

Category

Rehabilitation

2

Description

Control group: No intervention will be implemented.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Zahrasadat Hoseini

Street address

Poursina Hospital, Poursina Crossroad

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masood Yunesian

Street address

Tehran University of Medical Sciences, at the corner of Ghods St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

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Position

Ph.D in Nursing, faculty Member

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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