

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Effects of Functional Stretching Exercises on the Neural and Mechanical properties of the Spastic Medial Gastrocnemius Muscle in Different Periods in stroke patients.

#### Protocol summary

##### Summary

**Aim:** Investigating the effects of functional stretching exercises on the neural and mechanical properties of the spastic medial gastrocnemius muscle in different periods in stroke patients. Major eligibility criteria: Unilateral brain stroke; Existence of spasticity in ankle; Ability to walk with or without assistive device; Good cognitive status; Good general health status; Good range of movement in ankle joint; Lack of pain in ankle; Not attending in any sport activities or physiotherapy; Not taking any spasmolytic medicine; No existence of any other neurological disease such as parkinson.

**Participants:** Patients with brain stroke in 2015 that have been admitted as outpatient in physiotherapy clinics.

**Sample size:** Forty patients that will be assigned to two interventional group according to the period of less than 12 months and above 12 months passed from their brain accident. Twenty patients including mixed number of patients with less and above 12 months from their brain accident will also be recruited as control group. Intervention:

Functional stretching will be applied to both intervention groups. No stretching will be applied to control group.

**Primary outcomes:** The Hmax/Mmax and H reflex delay time will be measured in medial gastrocnemius muscle in all groups using electromyography device at the baseline, after and one month after the intervention.

Pennation angle and thickness of the relative muscle will be measured by sonography.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201603084738N5**

Registration date: **2016-05-30, 1395/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-30, 1395/03/10

##### Registrant information

###### Name

Khosro Khademi Kalantari

###### Name of organization / entity

Shahid Beheshti university of medical sciences,  
Faculty of Rehabilitation

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7756 1411

###### Email address

k\_khademi@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2015-05-31, 1394/03/10

##### Expected recruitment end date

2016-05-30, 1395/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of Functional Stretching Exercises on the Neural and Mechanical properties of the Spastic Medial Gastrocnemius Muscle in Different Periods in stroke patients.

**Public title**

The Effect of Muscular Stretching on Muscle Spasticity After Brain Stroke

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Unilateral brain stroke; Spasticity in ankle based on the Persian version of modified modified Ashworth scale (MMAS.>1); Ability to walk with or without assistive devices ; Adequate mental status with score above 24 according to Persian version of Mini-Mental Status Scale ; Adequate general health ; enough range of motion in ankle joint. Exclusion criteria: Contracture and deformity in ankle joint; Pain in lower limb; participation in sport activities or physical therapy ; Using anti spasticity medicine; Other neurological diseases such as Parkinson.

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary IDs**

empty

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

Shahid Beheshti University of Medical Sciences

**Street address**

Building number 2, Shahid Beheshti University of Medical Sciences, Velenjack, next to Taleghani Hospital

**City**

Tehran

**Postal code****Approval date**

2015-12-27, 1394/10/06

**Ethics committee reference number**

IR.SBMU.REC.1394.133

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

Brain stroke

**ICD-10 code**

I64

**ICD-10 code description**

Stroke, not specified as haemorrhage or infarction

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

H reflex delay

**Timepoint**

baseline, after and one month after intervention

**Method of measurement**

EMG

**2****Description**

Hmax/Mmax ratio

**Timepoint**

baseline, after and one month after intervention

**Method of measurement**

EMG

**3****Description**

fascicle length

**Timepoint**

baseline, after and one month after intervention

**Method of measurement**

sonography

**4****Description**

penetration angle

**Timepoint**

baseline, after and one month after intervention

**Method of measurement**

sonography

**Secondary outcomes****1****Description**

spasticity score

**Timepoint**

baseline, after and one month after intervention

**Method of measurement**

MMAS

## Intervention groups

### 1

#### Description

Dynamic stretching of gastrocnemius muscle will be applied to intervention group with the history of less than 12 months from brain stroke.

#### Category

Rehabilitation

### 2

#### Description

Dynamic stretching of gastrocnemius muscle will be applied to intervention group with the history of more than 12 months from brain stroke.

#### Category

Rehabilitation

### 3

#### Description

No stretch will be applied to control group.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Rehabilitation, Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Khosro Khademi Kalantari

##### Street address

School of Rehabilitation, Opposite to Bou Ali Hospital, Damavand Road, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Afshin Zarghi

##### Street address

Building number 2, Shahid Beheshti University of Medical Sciences, Velenjak, next to Taleghani Hospital

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

School of Rehabilitation, Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Khosro Khademi Kalantari

##### Position

Professor

##### Other areas of specialty/work

##### Street address

School of Rehabilitation, Opposite to Bou Ali Hospital, Damavand Road, Tehran, Iran

##### City

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##### Postal code

##### Phone

+98 21 7756 1407

##### Fax

##### Email

Khosro\_khademi@yahoo.co.uk

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

school of rehabilitation, Shahid Beheshti University of Medical sciences

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khosro khademi kalantari

##### Position

Professor

##### Other areas of specialty/work

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##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

School of Rehabilitation, Shahid Beheshti University of  
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**Full name of responsible person**

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**Position**

professor

**Other areas of specialty/work****Street address**

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**City**

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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*