

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The efficacy of modify constraint-induced movement therapy and functional electrical stimulation on upper extremity function in patients with stroke in sub acute stage of recovery

Protocol summary

Study aim

Effect of constraint-induced motion therapy modification and functional electrical stimulation on the upper limb function of patients with stroke in the subacute stage of recovery

Design

Clinical trial, Two parallel groups randomised trial, blind, sample size 56

Settings and conduct

Initially, the severity of the stroke will be determined by NIHSS criteria. Then, the patients will be evaluated by WMFT and assign into two groups using Permuted block randomization methods. In one group FES plus exercise, and for the other group FES plus exercise and CIMT will be performed. After the end of treatment, both groups of patients will be assessed again by WMFT, with respect to performance and duration of motor tasks. Also, after one month, the outcomes are re-evaluated. At the interval between the end of the treatment and 1 month follow-up, FES plus exercise will continue for both groups.

Participants/Inclusion and exclusion criteria

Patients with lacunar stroke have entry conditions and patients with brain hemorrhage are not included in the study.

Intervention groups

All patients receive FES after being admitted to one of the treatment groups. Electric stimulation will be used for ten sessions each day and a total of 10 days for patients. All patients will have at least 10 days exercise in the field of lce and shoulder elbow and shoulder in the clinic as well as once at home. All patients in the target group will use one of the commonly used CIMT methods. The patient will use this glove for a healthy upper limb for 10 days and 6 hours a day.

Main outcome variables

The overall performance score of the tests is based on the Wolf test The time of the tests is based on the Wolf

test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N4**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **prospective**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

Registration date

2018-04-24, 1397/02/04

Registrant information

Name

Kamran Ezzati

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy of modify constraint-induced movement therapy and functional electrical stimulation on upper extremity function in patients with stroke in sub acute stage of recovery

Public title
The effects of modified constraint-induced movement therapy and functional electrical stimulation in stroke patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The history of lacunar brain stroke, which is diagnosed on the basis of CT scans and lasts from one week to three months Middle-aged men and women (over 45 years of age) with diagnosis of stroke The mother tongue is Persian and is able to understand oral instructions It is able to open the wrists and fingers and two other fingers at 10 degrees Patients who are able to maintain balance in sitting conditions. That means they can sit up to 30 seconds without help and support The severity of the disease will be, according to the National Institutes of Health Stroke Scale(NIHSS)scale, an average NIHSS = 8-16
Exclusion criteria:
 Patients with a history of arm or hand disability Patients with shoulder and shoulder pain Patients with cognitive impairment or, in other words, Mini-Mental State Examination(MMSE) scores below 24 Patients with a history of other neurological diseases including Parkinson's disease, multiple sclerosis and traumatic brain injury in their medical records. Patients with cerebral hemorrhage

Age
From **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
The grouping method will be Permuted block randomization . So, blocks of 10 people including 5 participants in the intervention group and 5 participants in the control group are allocated.

Blinding (investigator's opinion)
Single blinded

Blinding description

The examiner won't know anything about the kind of treatment. Therapists will also not know anything about grouping and kind of interventions.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Guilan University of Medical Sciences

Street address

5th floor, Central office of Guilan University of Medical Sciences, Namjoo St., Rasht, Iran

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.GUMS.REC.1396.463

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

The overall performance score of the tests is based on the Wolf test. According to Wolf's ability to perform an arm, the scores are between zero and five, with a score of 0 means the absence of the affected limb and a score of five, meaning a move close to the normal. Finally, the median time and total scores will be recorded as a total score.

Timepoint

Before the intervention, 10 and 30 days after the intervention

Method of measurement

2

Description

The time of the tests will be recorded based on the Wolf test according to the Wolf Mean Time Scale and the total performance scores as the total score.

Timepoint

Before the intervention, 10 and 30 days after the intervention

Method of measurement

Wolf's Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For this group of patients, functional electrical stimulation (FES) and exercise with modified constraint induced movement therapy will performed

Category

Rehabilitation

2

Description

Control group: For this group of patients, FES and exercise will performed

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina hospital

Full name of responsible person

Kamran Ezzati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

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Web page address

http://www.gums.ac.ir/research

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Kamran Ezzati

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Some data will be shared if required.

When the data will become available and for how long

Accessibility about 6 month after publishing the results.

To whom data/document is available

Researchers in scientific and academic institutes

Under which criteria data/document could be used

More analysis in specific conditions

From where data/document is obtainable

2-Email 2- Telephone

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

A letter with the reasons of requiring data

Comments