Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 lice 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)

Phone

+98 13 3369 0099

Email address

kamranezzati@gums.ac.ir

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

Wolf's Questionnaire

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
Street address
Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht
City
Rasht
Province
Guilan
Postal code
4193731943
Phone
+98 13 3332 2444
Fax
+98 13 3333 9842
Email
Ez_kamran@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Shadman Nemati
Street address
Deputy of research, Opposie to Azodi Stadium, Namjoo St, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3333 5821
Fax
+98 13 3332 4168
Email
Research@gums.ac.ir
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
Physiotherapy
Street address
Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht
City

Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3332 2444
Email
Ez_kamran@yahoo.com

Person responsible for scientific 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
Physiotherapy
Street address
Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht
City
Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3332 2444
Email
Ez_kamran@yahoo.com

Person responsible for updating data

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
Physiotherapy
Street address
Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht
City
Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13322444
Email
Ez_kamran@yahoo.com

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