

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Functional Electrical Stimulation and Functional Exercise Therapy on Treatment of Ischemic Stroke

Protocol summary

Study aim

The aim of this research is comparing the effect of functional electrical stimulation and functional exercise therapy on treatment of ischemic stroke. This study is a single-blind clinical trial. Thirty three patients will refer to the Fattemieh physiotherapy clinic in Rafsanjan . Three intervention of this study are functional electrical stimulation, functional exercise therapy and conventional therapy of physiotherapy.

Design

In this study 3 group treatments will done through parallel design and assesses during 1st, 10th sessions and one month later.

Settings and conduct

Assessor evaluates the patients refer to fathemieh physiotherapy clinic and divided them into 3 equal groups.

Participants/Inclusion and exclusion criteria

Inclusion: aged 30-65 years; one month following the first stroke; having spasticity in extremities; can be able to understand and corporate. Exclusion: cognitive and speech disorders; aphasia; alzheimer; bedriden prior to stroke; diseases of heart and pacemaker and leaving of study.

Intervention groups

First group will receive functional electrical stimulation by stimulator set connect to extremities of patients, 620F model made in Iran and functional current for 20 minutes. Second group will receive functional exercise therapy includes detect and constant exercise during 30 minutes for strengthening of muscles of upper and lower extremities, standing and gait Third group (conventional physiotherapy) are include range of motion exercise therapy and stimulator set (620F model, made in Iran) and faradic current applies for 20 minutes)

Main outcome variables

Intensity of spasticity, strengthening of grasp, ability of walking, assesses of disability level and shoulder pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100129003220N9**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name

Dadollah Shahimoridi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Functional Electrical Stimulation and Functional Exercise Therapy on Treatment of Ischemic Stroke

Public title

The effect of functional electrical stimulation and functional exercise on ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion: aged 30-65 years; one month following the first stroke; having spasticity in extremities; can be able to understand and cooperate.

Exclusion criteria:

Exclusion are include cognitive and speech disorders; aphasia; alzheimer; bedriden prior to stroke; diseases of heart and pacemaker and leaving of study.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

Assessor evaluates the patients based on inclusion criteria, then he divides them to random permuted blocks methods in 3 equal groups and refer to therapist.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study assessor is different from therapist, assessor is not aware of treatment but therapist and patient are aware of the treatment.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ettics of committe of Rafsanjan University of Medical Sciences

Street address

Central Organization of Rafsanjan University of

Medical Sciences, Emam Ali Blvd.

City

Rafsanjan

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7717893591

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.RUMS.REC.1396.217

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Spasticity intensity

Timepoint

1st, 10th sessions and one month later

Method of measurement

By modified Ashworth Scale (MAS)

2

Description

Strengthening of grasp

Timepoint

1st, 10th sessions and one month later

Method of measurement

By dinamometer

3

Description

Ability of walking

Timepoint

1st, 10th sessions and one month later

Method of measurement

Request the patient to walk

4

Description

Assesses of level of disability

Timepoint

1st, 10th sessions and one month later

Method of measurement

By modified Rankin Scale (MRS)

5

Description

Shoulder pain

Timepoint

1st, 10th sessions and one month later

Method of measurement

By Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First group will receive functional electrical stimulation by stimulator set connect to extremities of patients, 620F model made in Iran and functional current using for 20 minutes.

Category

Rehabilitation

2

Description

Intervention group: Second group will receive functional exercise therapy includes detect and constant exercise during 30 minutes for strengthening of muscles of upper and lower extremities, standing and walking

Category

Rehabilitation

3

Description

Intervention group: Third group (conventional physiotherapy) are include range of motion exercise therapy and stimulator set (620F model, made in Iran) and faradic current applies for 20 minutes)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fattemieh physiotherapy clinic

Full name of responsible person

Dadollah Shahimoridi

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Alley 17, moalem street

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Hamid Hostad Ebrahimi

Street address

Educational Assistant, Central Organization of Rafsanjan University of Medical Sciences, Emam Ali Blvd

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dadollah Shahimoridi

Position

Instructor/Academic member

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dadollah Shahimoridi

Position

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Latest degree

Master

Other areas of specialty/work

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Web page address**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

Published in medical journals and the Internet.

When the data will become available and for how long

It is possible after a year.

To whom data/document is available

All medical and non-medical researchers have access to data.

Under which criteria data/document could be used

It can be used to increase science and clinical application.

From where data/document is obtainable

It can be used to increase physiotherapy science and clinical application.

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

It is accessible through the Internet and medical journals by giving the keyword.

Comments