

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 cooperate. 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)

##### Phone

+98 39 1822 0040

##### Email address

d\_shahimoridi@rums.ac.ir

##### 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

##### Province

Kerman

##### Postal code

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

##### **Street address**

Alley 17, moalem street

##### **City**

Rafsanjan

##### **Province**

Kerman

##### **Postal code**

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##### **Phone**

+98 34 3435 5286

##### **Fax**

+98 34 3428 0097

##### **Email**

d\_shahimoridi@rums.ac.ir

##### **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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##### **Email**

hostadebrahimi@yahoo.com

#### **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**

Rafsanjan University of Medical Sciences

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**Position**

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Master

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dadollah Shahimoridi

**Position**

Academic member

**Latest degree**

Master

**Other areas of specialty/work**

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**Fax**

+98 34 3428 0097

**Email**

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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**