Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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 corporate.

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
7717893591
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
City
Rafsanjan
Province
Kerman
Postal code
7717893591
Phone
+98 34 3428 0097
Fax
+98 34 3428 0097
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
Street address
Education Assistant, Centeral Organization of Rafsanjan University of Medical Sciencec, Emam Ali Blvd.
City
Rafsanjan
Province
Kerman
Postal code
7717893591
Phone
+98 34 3435 5286
Fax
+98 34 3428 0097
Email
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
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Fax
+98 34 3428 0097
Email
d_shahimoridi@rums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
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d_shahimoridi@rums.ac.ir
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