

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of contralateral limb cross education and high frequency repetitive trans-cranial magnetic stimulation on functional indices of affected upper limb in subacute stroke patients

Protocol summary

Summary

The purpose of this study is comparison of 4 techniques on function of hand in stroke patients. The sample size was calculated as 40 hemiplegic patients, that after filling out a consent form, subjects participated in experiments. The subjects are randomly assigned into 4 groups. For first group routine physiotherapy, for the second group physiotherapy & cross education, for the third group physiotherapy & rTMS, and for the fourth group physiotherapy, cross education & rTMS is applied. Duration of treatment is 10 sessions (3 weeks). Function of hand is measured before and after treatments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011726056N1**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Farzaneh Moslemi Haghighi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research affairs of Shiraz University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of contralateral limb cross education and high frequency repetitive trans-cranial magnetic stimulation on functional indices of affected upper limb in subacute stroke patients

Public title

The effect of cross education and trans-cranial magnetic stimulation in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hemiplegic patients aged between 30-65 years; hemiplegia after first stroke; having 22-44 scale in Fugle- Meyer Scale ; Exclusion criteria: having fracture, dislocation and subluxation in upper extremity, rheumatoid diseases in upper extremities; other neurologic diseases; limiting range of motion in upper extremity; epilepsy; cardiac arrhythmia; implant in skull; aphasia

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Blv.

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SUMS.REC.1394.136

Health conditions studied

1

Description of health condition studied

hemiplegia

ICD-10 code

G81.9

ICD-10 code description

Hemiplegia, unspecified

Primary outcomes

1

Description

grip strength

Timepoint

before and after intervention

Method of measurement

grip dynamometer

2

Description

pinch strength

Timepoint

before and after intervention

Method of measurement

Pinch gauge

3

Description

dexterity

Timepoint

before and after intervention

Method of measurement

Box and Block Test

4

Description

muscle tone

Timepoint

before and after intervention

Method of measurement

Modified Ashworth Scale

5

Description

functional movement of hand

Timepoint

before and after intervention

Method of measurement

Fugle- Meyer Scale

Secondary outcomes

empty

Intervention groups

1

Description

for first group (control group), routine physiotherapy for affected upper extremity of hemiplegia is applied in 10 sessions ,3 times a week. routine physiotherapy sessions include joints range of motions, gentle stretching of hapertonic muscles, strengthening of muscle weakness, learning of activity daily living and functional electrical stimulation.

Category

Treatment - Other

2

Description

For the second group,The subject is seated, both arms are relaxed and unaffected elbow is flexed to a right angle, with the unaffected forearm is in nutral position and resting on a table. maximal grip force of unaffected hand is measured by grip dynamometer. Then, subject

grasps unaffected hand with 60-70% of maximal voluntary contraction 30 times in each sessions. Each patient receives 10 treatment sessions (3 times a week) of cross education technique.in addition, Routine physiotherapy is performed in each session.

Category

Treatment - Other

3

Description

For the third group, HF- rTMS Is applied over the primary motor cortex for the fingers of the lesional hemisphere. Each rTMS session consists of 2000 pulses. Site of stimulation on the skull is defined as the location where the largest motor evoked potentials of the first dorsal interosseous muscle in the unlesioned upper extremity are elicited on electromyography. the intensity of stimulation is set at 90% of the motor threshold of the first dorsal interosseous muscle. Frequency of stimulation is 20 Hz and .Each patient receives 10 treatment sessions (3 times a week) of rTMS. Routine physiotherapy is performed after the application of rTMS sessions.

Category

Treatment - Other

4

Description

For the fourth group cross education (similar to second group), HF-rTMS (similar to third group) and physiotherapy is applied in each session.Each patient receives 10 treatment sessions (3 times a week).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Department of Rehabilitation Sciences Faculty

Full name of responsible person

Farzaneh Moslemi Haghighi

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Zand Blv.Shiraz, Fars, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Moslemi Haghighi

Position

academic member

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty