

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation and comparison of the effect of cross education training of unaffected upper limb on neurophysiological parameters and functional indices of affected upperlimb in sub-acute stroke patients

Protocol summary

Summary

The aim of this study is to compare effect of cross education training of unaffected upper limb versus conventional rehabilitation on improvement in neurophysiological parameters and functional indices of affected upperlimb among patients who had sub-acute stroke within the previous 2 weeks to 3 months. In a double blind randomized clinical trial, twenty patients with First-ever unilateral stroke, between 18-80 years old are included in the study. They are excluded if they have Contraindications to transcranial magnetic stimulation or severe cognitive impairment, aphasia and depression. Ten patients in intervention group receive both conventional rehabilitation (40 min per session, 3 days a week for 4 weeks) and cross education training of unaffected wrist extensor muscles. Ten Patients in control group only receive the same conventional rehabilitation as intervention group. Patients and investigators are masked to treatment assignment. Neurophysiological parameters (rest motor threshold, active motor threshold, recruitment curve, cortical silent period and ipsilateral silent period) are studied by transcranial magnetic stimulation, before intervention and 1 month after beginning intervention. Also functional outcomes including performance in activities of daily living, spasticity, wrist extensor muscle strength and motor function are evaluated by Modified Barthel Index, Modified Modified ashworth scale, Isokinetic dynamometer biodex device and Fugl-Meyer Assessment respectively before and after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102430477N1**
Registration date: **2016-12-01, 1395/09/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-01, 1395/09/11

Registrant information

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of cross education training of unaffected upper limb on neurophysiological parameters and functional indices of

affected upperlimb in sub-acute stroke patients

Public title
Effect of Rehabilitation in Stroke Recovery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: First-ever stroke resulting in right or left upper limb paresis and stroke had occurred between 2 weeks and 3 months; CT or MRI documenting a monohemispheric lesion as determined by a neurologist; Age between 18 and 80 years old; Patients with right-hand dominant according to Edinburg handedness scale; Patients with severe motor deficit of wrist extensor (score of 2 or less in strength test scale); Patients with severe to moderate motor impairment of affected upper limb (points less than 45 in items related to upper limb motor function); Not taking anti-spasticity drugs.
Exclusion criteria: Other neurological diseases; Presence of pain, fracture, surgical history and joint dislocation of upper extremity; Contraindications to transcranial magnetic stimulation (TMS) including cardiac pacemaker, metal implants in skulls or eye, past history of seizure ; Presence of dementia, severe cognitive impairment (score of less than 24 points on the mini-mental status examination), aphasia and depression that made the patient uncooperative; Current use of drugs that could affect the excitability of the motor cortex, such as anti-epileptic and psychoactive drugs.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

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

Ethics committee of Shiraz University of Medical

Sciences
Street address
Zand Street, Shiraz
City
Shiraz
Postal code
Approval date
2016-07-17, 1395/04/27
Ethics committee reference number
IR.SUMS.REC.1395.70

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

164

ICD-10 code description

stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

rest motor threshold

Timepoint

before intervention, after intervention

Method of measurement

TMS device

2

Description

active motor threshold

Timepoint

before intervention, after intervention

Method of measurement

TMS device

3

Description

recruitment curve

Timepoint

before intervention, after intervention

Method of measurement

TMS device

4

Description

Cortical silent period

Timepoint

before intervention, after intervention

Method of measurement

TMS device

5

Description

Ipsilateral silent period

Timepoint

before intervention, after intervention

Method of measurement

TMS device

Secondary outcomes

1

Description

measuring performance in activities of daily living

Timepoint

before intervention, after intervention

Method of measurement

Modified Barthel Index

2

Description

spasticity

Timepoint

before intervention, after intervention

Method of measurement

modified modified ashworth scale

3

Description

wrist extensor muscle strength

Timepoint

before intervention, after intervention

Method of measurement

isokinetic dynamometer biodex device

4

Description

assessment of motor function

Timepoint

before intervention, after intervention

Method of measurement

Fugl-Meyer Assessment

Intervention groups

1

Description

control group: conventional rehabilitation (electrical stimulation of paretic limbs, combined functional patterns of affected upper limb, gentle stretch of hypertone muscle, balance exercise, gait training, and activities of daily living training) 40 min per session, 3 days a week for 4 weeks

Category

Rehabilitation

2

Description

intervention group: conventional rehabilitation (electrical stimulation of paretic limbs, combined functional patterns of affected upper limb, gentle stretch of hypertone muscle, balance exercise, gait training, and activities of daily living training) 40 min per session, 3 days a week for 4 weeks and cross education training (strength training of wrist extensor muscles of unaffected side, five sets of 6 maximum effort concentric- eccentric wrist extension repetitions and rest is 2 min between sets) 3 days a week for 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Nasrin Salehi Dehno

Street address

Zand Street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Shiraz University of Medical Science

Full name of responsible person

Seyed Basir Hashemi

Street address

Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

94-01-06-11135

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

Yes

Title of funding source

Vice Chancellor of Research, Shiraz University of Medical Science

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

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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