Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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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
Effct 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 Edingburg 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
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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

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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