

# 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

Registration timing: **prospective**

#### 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

Last update:

Update count: **0**

#### Registration date

2016-12-01, 1395/09/11

#### Registrant information

##### Name

Nasrin Salehi Dahno

##### Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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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

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102430477N1**

Registration date: **2016-12-01, 1395/09/11**

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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*