

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of electrical interferential current stimulation and electrical acupuncture in the management of hemiplegic shoulder pain and disability following ischemic stroke

#### Protocol summary

##### Summary

Objectives: 1-Comparison of electrical interferential current stimulation and electrical acupuncture in the treatment of hemiplegic shoulder pain in ischemic stroke patients; 2- Comparison of electrical interferential current stimulation and electrical acupuncture in the treatment of shoulder functional disability in ischemic stroke patients. Design: single- blinded randomized clinical trial Participants including major eligibility criteria: patients who are suffering from hemiplegic shoulder pain due to ischemic stroke with duration of one month to one year after stroke with or without subluxation will be selected. Patients with history of physiotherapy within the previous one month, history of local injection of steroid/Botox into shoulder joint, presence of pacemaker or skin lesions in shoulder area, intra cerebral hemorrhage or impaired cognition will be excluded. Setting, conduct and interventions: Eligible patients who are referred to physiotherapy center of Tabriz Imam-Reza university hospital will be randomly assigned in two groups of 20 people. In both groups, anteroposterior and lateral x-ray will be taken before treatment for evaluation of shoulder subluxation. All patients in both groups undergone conventional physical therapy including superficial heat therapy (infra-red), faradic electrical stimulation (FES) for shoulder antigravity muscles and exercise programs such as range of motion and strengthening exercises for a total of ten-session period. Then, two groups will be separated and compared regarding the following agents: in group A, additional treatment including acupuncture concomitant electrical stimulation will be performed. Acupuncture needles with 25 \*0.25 sizes will be inserted inside the acu points: SI 10-12 (supraspinatus fossa), Du 14 (2cm lateral to C7 cervical spinus process), LI 14 (deltoid insertion), LI 10-11 (lateral epicondyl), Du 20( vertex of head), LI 4 (web of first dorsal interspaces of

hand), GB20( top of upper trapezius) and two tender points of each patient. Electrical acupuncture will be done for 20 minutes by expert physiatrist 2 times a week for 5 weeks. In group B, interferential current therapy with (IFC) using carrier frequency of 100 HZ with four electrodes attached to infraspinatus and serratus anterior via one channel and attached to supraspinatus and deltoid muscles via second channel will be performed. Electrodes arrangement will be crossed shape and cloverleaf current will be applied 3 times a week for 3 weeks by an expert therapist. Variables of main outcome measure: Function and pain will be assessed by shoulder pain and disability index (SPADI) questionnaire and range of motion will be measured for active and passive flexion, abduction, internal and external rotation by goniometry. All assessments will be done before and after treatment and finally all obtained data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602153217N10**

Registration date: **2016-07-16, 1395/04/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-16, 1395/04/26

##### Registrant information

##### Name

Fariba Eslamian

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

**Phone**

+98 41 3337 3967

**Email address**

eslamianf@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research of Tabriz University of Medical science

**Expected recruitment start date**

2016-07-15, 1395/04/25

**Expected recruitment end date**

2016-11-15, 1395/08/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of electrical interferential current stimulation and electrical acupuncture in the management of hemiplegic shoulder pain and disability following ischemic stroke

**Public title**

Electrical stimulation vs acupuncture for hemiplegic shoulder pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: patients with hemiplegic shoulder pain due to Ischemic stroke, who have been affected within the one month to one year after stroke. Exclusion criteria: 1-physiotherapy within the previous month ;2- history of local steroid/botox injection into shoulder joint; 3-presence of pacemaker in heart; 4-local skin lesions in shoulder area; 5-intracerebral hemorrhage ; 6-impaired cognition.

**Age**

From **50 years** old to **80 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)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

ندارد

**Secondary trial Id**

ندارد

**Registration date**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Daneshgah Ave., executive field of Tabriz University of Medical Sciences, vice chancellor for research of Tabriz university of medical Sciences,Ethics committee.

**City**

Tabriz

**Postal code****Approval date**

2016-02-02, 1394/11/13

**Ethics committee reference number**

TBZMED.REC.1394.1004

**Health conditions studied****1****Description of health condition studied**

hemiplegic shulder pain due to stroke

**ICD-10 code**

I69.4

**ICD-10 code description**

Sequelae of stroke, not specified as haemorrhage or infarction

**Primary outcomes****1****Description**

shoulder pain and disability intensity

**Timepoint**

week0-week 5

**Method of measurement**

questionnaire of " shoulder pain and disability Index"

**Secondary outcomes**

## 1

### Description

shoulder range of motion

### Timepoint

week 0-week 5

### Method of measurement

Goniometry

## Intervention groups

## 1

### Description

All patients in both groups undergone conventional physical therapy including superficial heat therapy (infra-red), faradic electrical stimulation (FES) for shoulder antigravity muscles and exercise programs such as range of motion and strengthening exercises for a total of ten-session period. Then, two groups will be separated and compared regarding the following agents: in group A, additional treatment including acupuncture concomitant electrical stimulation will be performed. Acupuncture needles with 25 \*0.25 and 25\*0.30 sizes will be inserted inside the these acu points: SI 10-12 (supraspinatus fossa), Du 14 (2cm lateral to C7 cervical spinus process), LI 14 (deltoid insertion), LI 10-11 (lateral epicondyl), Du 20( vertex of head), LI 4 (web of first dorsal interososes of hand), GB20( top of upper trapezius) and two tender points of each patient. Electrical acupuncture will be done for 20 minutes by expert physiatrist 2 times a week for 5 weeks.

### Category

Treatment - Other

## 2

### Description

In group B ( comparison group), interferential current therapy with (IFC) using carrier frequency of 100 HZ with four electrodes attached to infraspinatus and serratus anterior via one channel and attached to supraspinatus and deltoid muscles via second channel will be performed. Electrodes arrangement will be crossed shape and cloverleaf current will be applied 3 times a week for 3 weeks by an expert therapist.

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza University Hospital

#### Full name of responsible person

Fariba Eslamian

#### Street address

Golgasht Ave.,Imam Reza university hospital,Physical medicine and rehabilitation ward

#### City

Tabriz

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice chancellor for research ,Tabriz university of Medical Sciences

#### Full name of responsible person

Neda Dolatkah

#### Street address

Golgasht Ave, Vice chancellor for research of Tabriz university of Medical Sciences, Physical medicine and rehabilitation research center

#### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research ,Tabriz 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

Tabriz university of medical sciences

#### Full name of responsible person

Parvin Darabi

#### Position

Resident of physical medicine and rehabilitation

#### Other areas of specialty/work

#### Street address

Golgasht Ave,Imam Reza hospital,Physical medicine and rehabilitation department.

#### City

Tabriz

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+98 41 3337 3967

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parvin2010d@gmail.com

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fariba Eslamian

**Position**

Associate professor of physical medicine and rehabilitation

**Other areas of specialty/work****Street address**

Golgasht Ave, Imam Reza Hospital, Physical medicine and rehabilitation department.

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of medical sciences

**Full name of responsible person**

Fariba Eslamian

**Position**

Associate professor of physical medicine and rehabilitation

**Other areas of specialty/work****Street address**

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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*