

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The Effectiveness of Dry Needling on Upper and Lower Dysfunction on stroke patients

#### Protocol summary

##### Study aim

The Effect of Dry Needling on Upper and Lower Limb Dysfunction of Stroke Patients

##### Design

Double blind, sham controlled, randomized

##### Settings and conduct

A randomized clinical trial was conducted on 24 patients with a stroke who had been identified with a definitive diagnosis in Imam Khomeini Hospital and had hemiplegia. Patients are randomly selected randomly in one of the two intervention groups and the control group based on entry criteria and consent to participate in the research.

##### Participants/Inclusion and exclusion criteria

18-75 years; first brain stroke; Sufficient communication skills to show yes / no verbally or through gestures; be able to walk for at least 10 meter; unilateral hemiparesis.

##### Intervention groups

A specialist who has expertise in dry needling, will deliver three sessions of dry needling on the flexor carpiradialis and flexor carpiulnaris muscles of the upper extremity and gastrocnemius muscle of the lower extremity on the affected side the intervention group. Evaluation the effect of dry needling on the spasticity of aforementioned muscles on the affected side will do immediately after last session of dry needling and after 1 month of baseline, in comparison with baseline information gained before doing dry needling in the intervention group. All these procedures will do for control group but using placebo dry needling instead of dry needling for control group.

##### Main outcome variables

spasticity (MMAS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171111037388N4**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **retrospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

##### Registration date

2019-04-07, 1398/01/18

##### Registrant information

###### Name

Ardalan Shariat

###### Name of organization / entity

TUMS

###### Country

Iran (Islamic Republic of)

###### Phone

+98 939 861 4772

###### Email address

a-shariat@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-01, 1397/03/11

##### Expected recruitment end date

2019-02-01, 1397/11/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effectiveness of Dry Needling on Upper and Lower Dysfunction on stroke patients

##### Public title

The Effectiveness of Dry Needling on Spasticity

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

first brain stroke Sufficient communication skills to show yes / no verbally or through gestures be able to walk for at least 10 meter MMAS score equal or more than one unilateral hemiparesis

### Exclusion criteria:

unable patients to follow the instructions severe musculoskeletal disorders (For example, severe osteoporosis, arthritis} psychiatric disorders requiring drug therapy cognitive disorders contraindication to dry needling using anti-spastic drugs

## Age

From **18 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **24**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Based on the random number table, patients are placed in one of two groups.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients are not aware of being in the intervention group or the control group. The control group will receive the intervention once the study finished. In addition, both group participate in their conventional therapies.

Measurements are performed by an assessor who does not know the training protocols that each group has done.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

committee Ethics Committee of Tehran University of Medical Sciences

## Street address

No 7, Al-e-Ahmad Highway, Tehran, IR Iran

## City

Tehran

## Province

Tehran

## Postal code

14395-578

## Approval date

2019-01-05, 1397/10/15

## Ethics committee reference number

IR.TUMS.VCR.REC.1397.721

## Health conditions studied

### 1

#### Description of health condition studied

Brain Stroke

#### ICD-10 code

164

#### ICD-10 code description

Stroke, not specified as hemorrhage or infarction

## Primary outcomes

### 1

#### Description

Walking speed

#### Timepoint

Baseline, immediately after treatment and after 4 weeks

#### Method of measurement

10 meter walking test

### 2

#### Description

spasticity

#### Timepoint

Baseline, immediately after treatment and after 4 weeks

#### Method of measurement

modified modified ashworth scale

### 3

#### Description

mobility

#### Timepoint

Baseline, immediately after treatment and after 4 weeks

#### Method of measurement

Timed up and go test

### 4

#### Description

hand dexterity

#### Timepoint

Baseline, immediately after treatment and after 4 weeks

#### Method of measurement

Box and Block test

## Secondary outcomes

### 1

**Description**

Balance

**Timepoint**

Baseline, immediately after treatment and after 4 weeks

**Method of measurement**

Single Leg Stance Test

### 2

**Description**

Daily living activity

**Timepoint**

Baseline, immediately after treatment and after 4 weeks

**Method of measurement**

Barthel index

### 3

**Description**

range of motion

**Timepoint**

Baseline, immediately after treatment and after 4 weeks

**Method of measurement**

goniometer

### 4

**Description**

pennation angle of gastrocnemius muscle

**Timepoint**

Baseline, immediately after treatment and after 4 weeks

**Method of measurement**

sonography

### 5

**Description**

gastrocnemius muscle thickness

**Timepoint**

Baseline, immediately after treatment and after 4 weeks

**Method of measurement**

sonography

## Intervention groups

### 1

**Description**

Intervention group: A specialist who has expertise in dry needling, will deliver three sessions of dry needling on the spastic muscles of the upper and lower extremities on the hemiplegic side with a 48 hours interval between sessions. At baseline, immediately after last session of dry needling and after 1 month of baseline, the blind assessor, expert physiotherapist, will perform the clinical tests.

**Category**

Treatment - Devices

### 2

**Description**

Control group: A specialist who has expertise in dry needling, will deliver three sessions of placebo dry needling on the spastic muscles of the upper and lower extremities on the hemiplegic side with a 48 hours interval between sessions. At baseline, immediately after last session of placebo dry needling and after 1 month of baseline, the blind assessor, expert physiotherapist, will perform the clinical tests.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Imam khomeini hospital

**Full name of responsible person**

Prof.Noureddin Nakhostin Ansari

**Street address**

Gharib Ave, Keshavarz blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

14395-578

**Phone**

+98 21 6119 0000

**Email**

nakhostin@tums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ramin Kordi, Research Vice-Dept. of Neuro Res Cen,  
Tehran University of Medical Sciences

**Street address**

No 7, Al-e-Ahmad Highway, Tehran, IR Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

14395-578

**Phone**

+98 21 8863 0227

**Fax****Email**

ramin\_kordi@tums.ac.ir

**Grant name**

Research Vice-Dept. of Neuroscience Research Center,  
Tehran University of Medical Sciences

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ardalan Shariat

**Position**

Post doctoral Fellow

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neurorehabilitation

**Street address**

alale ale ahmad, Sports Medicine Research Center

**City**

Tehran

**Province**

Tehran

**Postal code**

14395-578

**Phone**

+98 939 861 4772

**Email**

ardalansh2002@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ardalan Shariat

**Position**

post doctoral fellow

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neurorehabilitation

**Street address**

sports Medicine research center, jalale ale ahmad

**City**

Tehran

**Province**

Tehran

**Postal code**

14395-578

**Phone**

+98 939 861 4772

**Email**

ardalansh2002@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ardalan Shariat

**Position**

Post doctoral Fellow

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Jalale ale ahmad, Sports Medicine Research Center

**City**

Tehran

**Province**

Tehran

**Postal code**

14395-578

**Phone**

+98 939 861 4772

**Email**

ardalansh2002@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more data

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All the data will be shared after removing identification details of participants. We will publish the results as a scientific article without any name from participants.

**When the data will become available and for how long**

After finish the protocol, the article will be published and will be available permanently.

**To whom data/document is available**

data is only available for people working in academic institutions

**Under which criteria data/document could be used**

For academic purpose

**From where data/document is obtainable**

Ardalansh2002@gmail.com Dr.Ardalan Shariat

**What processes are involved for a request to access data/document**

Call to the corresponding author directly

**Comments**