# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jun 2026

## A comparison on the effects of a single session of brachialis and Flexor Carpi Radialis muscles' dry needling on spasticity and brain activities of patients after stroke based on fMRI findings.

## Protocol summary

**Study aim**

Determining the effectiveness of upper extremity dry needling in stroke patients. CNS changes comparison of dry needling of the brachialis and flexor carpi radialis muscles, as well as the comparison of the effect of distal muscle dry needling on the spasticity of the proximal muscle and the active/passive range of motion of the proximal joint and vice versa.

**Design**

A controlled, parallel-group, single-blind, clinical trial which randomized by computerized numbering and numbered sealed envelopes on 20 stroke patients.

**Settings and conduct**

Coordinating with the National Brain Mapping Lab(NBML) and presenting an outline of the research and conducting initial discussions with the supervisor and also the fMRI unit expert. Then making a deal with NBML and determining the time for the presence of researcher and patients to perform the intervention and data registration of brain activities, spasticity and active/passive range of motion of the wrist and elbow.

**Participants/Inclusion and exclusion criteria**

Middle-aged stroke patients, with hemiplegia of one half of the body, who have upper limb spasticity (at least score>=1 in the MMAS test) and have at least possible mental and physical ability to participate in the study, as well as dry needling treatment method and f-MRI diagnostic method will not be harmful for them.

**Intervention groups**

In this study there are two groups which both of them receive dry needling intervention. with the difference that one group undergoes dry needling in the brachialis muscle (as a proximal muscle) and the other group in the flexor carpi radialis muscle (as a distal muscle). In this situation, the control group becomes active, that is, each group while receiving the intervention is considered as the control of the other group.

**Main outcome variables**

Severity of spasticity (evaluated using the MMAS test)
Brain activity intensity (number of active voxels)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230123057192N1**
Registration date: **2023-02-14, 1401/11/25**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **0**

**Registration date**

2023-02-14, 1401/11/25

**Registrant information**

**Name**

Mahdi Seyfollahipoor

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8612 1931

**Email address**

m-seyfollahipoor@razi.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-03-01, 1401/12/10

**Expected recruitment end date**

2023-05-15, 1402/02/25

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A comparison on the effects of a single session of brachialis and Flexor Carpi Radialis muscles' dry needling on spasticity and brain activities of patients after stroke based on fMRI findings.

**Public title**
Effects of dry needling as a physiotherapy approach on brain activities and spasticity of patients after stroke.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
First ever stroke resulted in hemiplegia Age between 40 to 65 years MMAS Score of spasticity in related muscles should be at least 1
**Exclusion criteria:**
Previous treatment with nerve blocks, motor point injection with neurolytic agents for spasticity at any time, or with BTX-A in the 6 months preceding the study Existence of severe Cognitive and perceptual deficits History of dry needling in the past 6 months Contraindications to dry needling Cervical radiculopathy Contracture of related muscles Unwilling to take part in the study Contraindications to MRI
**Age**
From **40 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Concealed allocation by using a computer-generated randomised table of numbers created before data collection and then delivery of the secret sealed envelopes which include numbered cards. The therapist opens the envelope and performs the treatment according to the specified group.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
f-MRI unit expert as the first evaluator (collector of brain activity variable data) and also a physiotherapist as the second evaluator (collector of other variable data) in this research are blind to the treatment groups . In this way, both people only collect the data presented by the main researcher without knowing about the treatment and the related treatment group.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
In this study, both groups will be treated by dry needling, with the difference that the intervention for one group is for the brachialis muscle (as the proximal muscle) and in the other group for the flexor carpi radialis muscle (as the distal muscle).In this case, we have active control group, it means that each group receiving the intervention should be considered as a control for the other group.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
**Street address**
Central Organization of Tehran University of Medical Sciences, corner of Qods St., Keshavarz Boulevard
**City**
Tehran
**Province**
Tehran
**Postal code**
1417653761
**Approval date**
2023-01-18, 1401/10/28
**Ethics committee reference number**
IR.TUMS.FNM.REC.1401.140

## Health conditions studied

### 1

**Description of health condition studied**
Stroke, Hemiplegia, spasticity
**ICD-10 code**
G81.1
**ICD-10 code description**
Spastic hemiplegia

## Primary outcomes

### 1

**Description**
The severity of spasticity of the brachialis and flexor carpi radialis muscles, which is measured based on the MMAS test.
**Timepoint**
Before, immediately after and 30 minutes after the intervention
**Method of measurement**
Through the MMAS test by a physiotherapist who is

expert in patients with hemiplegia

**2**

**Description**
Severity of brain activity
**Timepoint**
Before, immediately after and 30 minutes after the intervention
**Method of measurement**
Analysis of fMRI findings after finger tapping

## Secondary outcomes

**1**

**Description**
Active/passive elbow and wrist range of motions
**Timepoint**
Before, immediately after and 30 minutes after the intervention
**Method of measurement**
Through a goniometer and by a physiotherapist familiar with the desired assessment

## Intervention groups

**1**

**Description**
Intervention group: Deep fast in and fast out method of dry needling in the brachialis muscle for 1 minute.
**Category**
Rehabilitation

**2**

**Description**
Intervention group: Deep fast in and fast out method of dry needling in the flexor carpi radialis muscle for 1 minute.
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Tehran University of Medical Sciences
**Full name of responsible person**
Seyed Mohsen Mir
**Street address**
School of rehabilitation of Tehran University of Medical Sciences, corner of Safi Alishah Ave., Piche shemiran, Enghelab Ave.
**City**
Tehran
**Province**
Tehran
**Postal code**
1148956111
**Phone**
+98 21 7753 5132
**Fax**
+98 21 7753 4133
**Email**
rehabilitation@tums.ac.ir
**Web page address**
https://rehab.tums.ac.ir/

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Akbar Fotouhi
**Street address**
Central Organization of Tehran University of Medical Sciences, corner of Qods St., Keshavarz Boulevard
**City**
Tehran
**Province**
Tehran
**Postal code**
1417653761
**Phone**
+98 21 8163 3102
**Email**
tumspr@tums.ac.ir
**Web page address**
**Grant name**
**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**
Mahdi Seyfollahipoor
**Position**
Student , Master of Science
**Latest degree**

Bachelor
**Other areas of specialty/work**
Physiotherapy
**Street address**
No.19, Jahad alley , Shariati Ave , Abbas abad
**City**
Tehran
**Province**
Tehran
**Postal code**
1558748611
**Phone**
+98 21 8612 1931
**Fax**
**Email**
m-seyfollahipoor@razi.tums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Noureddin Nakhostin Ansari
**Position**
Professor of Physiotherapy
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Physiotherapy
**Street address**
School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran
**City**
Tehran
**Province**
Tehran
**Postal code**
1148956111
**Phone**
+98 21 7753 3939
**Fax**
**Email**
nakhostin@sina.tums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Mahdi Seyfollahipoor
**Position**
Student , Master of Science
**Latest degree**
Bachelor
**Other areas of specialty/work**
Physiotherapy
**Street address**
No.19, Jahad alley , Shariati Ave , Abbas abad
**City**
Tehran
**Province**
Tehran
**Postal code**
1558748611
**Phone**
+98 21 8612 1931
**Fax**
**Email**
m-seyfollahipoor@razi.tums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
The raw data of research and its analysis will be available to the researchers if they request it.
**When the data will become available and for how long**
After the publication of articles resulting from the research.
**To whom data/document is available**
Researchers working in academic institutions.
**Under which criteria data/document could be used**
The data are only available to other researchers to study and evaluate treatment outcomes.
**From where data/document is obtainable**
Dr. Noureddin Nakhostin Ansari, Department of Physiotherapy, School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran, 09122979309, nakhostin@sina.tums.ac.ir
**What processes are involved for a request to access data/document**
By sending an official E-mail to the corresponding author, professor Noureddin Nakhostin Ansari(nakhostin@sina.tums.ac.ir) and request the data. The researcher will be answered as soon as possible
**Comments**