

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of one session vs three sessions of dry needling on wrist flexor muscles spasticity and motor function in patients with stroke

#### Protocol summary

##### Study aim

Comparing the effect of one session with three sessions per week of dry needling in reducing spasticity and improving motor function of stroke patients and determining the number of more effective treatment sessions per week.

##### Design

Randomized;single blind ;simple randomized controlled clinical trial was performed on 24 patients for manual randomization with random selection of evaluation sheets.

##### Settings and conduct

Arman Pouya Isfahan Physiotherapy, dry needling in ulnar and radial wrist flexor muscles in one session and three sessions per week, the evaluator has been blinded to the first and second groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, first experience of stroke, stroke hemiplegia, at least six months after stroke, spasticity in wrist flexor muscles, not taking any antispasmodics, ability to understand instructions  
Exclusion criteria: Contraindication of dry needle use, diabetes, any other neurological complication, cervical radiculopathy, fixed contractures in the wrist area, receiving other treatments at the same time, fear of dry needle, Botox injection To reduce spasticity over the past six months

##### Intervention groups

Participants are randomly divided into two groups. The group receives one session per week and the group three sessions per week for dry needling. The dry acupuncture technique is performed for the ulnar and radial flexor muscles of patients with a conical method and for a maximum of one minute for each point.

##### Main outcome variables

Active range of motion; Passive range of motion; Passive resistive torque; Severity of spasticity; Bronstrom

recovery stage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210116050047N1**

Registration date: **2021-02-22, 1399/12/04**

Registration timing: **prospective**

Last update: **2021-02-22, 1399/12/04**

Update count: **0**

##### Registration date

2021-02-22, 1399/12/04

##### Registrant information

##### Name

Fatemeh Alsadat Hasheminasab Zavareh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5437 6410

##### Email address

f-hasheminasab@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-05, 1399/12/15

##### Expected recruitment end date

2021-07-21, 1400/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of one session vs three sessions of dry needling on wrist flexor muscles spasticity and motor function in patients with stroke

**Public title**

Evaluation of the effect of dry needling in reducing wrist stiffness and improving motor function in stroke patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 18 years The first experience of a stroke Stroke-induced hemiplegia At least six months have passed since the stroke Spasticity in the flexor muscles of the wrist Do not take any antispasmodics Ability to understand instructions

**Exclusion criteria:**

contraindication of dry needles (such as anticoagulants, infections, bleeding) Diabetes Existence of any other neurological complication Cervical radiculopathy Fixed contractures in the wrist area Receive other treatments at the same time Fear of dry needles Botox injections to reduce spasticity during the last six months

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple random Russian is used to determine the research groups. First, a sheet is prepared in the specified number of samples, and on half of the sheets, the group writes one session in a week of dry needling and the other half of the group writes three sessions in a week of dry needling. The order of these sheets is distorted and when the samples are referred, one sheet is randomly removed for each person and the relevant group is determined based on the registered title. The evaluator performs the clinical tests in random order and completes the evaluation and is completely blind to the first and second groups. The therapist is another experienced physiotherapist who is fully trained to perform dry needling and performs the treatment.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this one-way blind study, the evaluator performs clinical tests in random order and completes the evaluation and is completely blind to the first and second groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

**Street address**

First Alley, Post Alley, 11 Khordad St., Mosalla Square

**City**

Zavareh

**Province**

Isfahan

**Postal code**

8441817716

**Approval date**

2020-12-22, 1399/10/02

**Ethics committee reference number**

IR.TUMS.FNM.REC.1399.158

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

Stroke

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Passive resistive torque

**Timepoint**

Before the intervention, after the end of the intervention, one week after the end of the intervention

**Method of measurement**

Hand held dynamometer

**Secondary outcomes****1****Description**

Spasticity

**Timepoint**

Before intervention, after intervention, one week after intervention

## Method of measurement

Modified Modified Ashworth Scale

## 2

### Description

Bronstrom recovery stage

### Timepoint

Before intervention, after intervention, one week after intervention

### Method of measurement

Six-stage system of patients' motor recovery

## 3

### Description

Active range of motion of the wrist

### Timepoint

Before intervention, after intervention, one week after intervention

### Method of measurement

Goniometer

## 4

### Description

Passive range of motion of the wrist

### Timepoint

Before intervention, after intervention, one week after intervention

### Method of measurement

Goniometer

## Intervention groups

### 1

#### Description

Intervention group: Three sessions of dry needling per week on the ulnar and radial flexor muscles of the wrist

#### Category

Treatment - Devices

### 2

#### Description

Control group: One dry needling session per week on the ulnar and radial flexor muscles of the wrist

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Arman Pouya Physiotherapy Clinic

##### Full name of responsible person

Fatemeh Alsadat Hasheminasab Zavareh

##### Street address

Arman Pouya Physiotherapy Clinic, not far from

Mosalla Square, Ayatollah Taleghani St., Vahdat Square

##### City

Zavareh

##### Province

Isfahan

##### Postal code

8441817716

##### Phone

+98 31 5437 6410

##### Email

fhz1373@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

MOHAMMAD ALI SAHRAIAN

##### Street address

Vice Chancellor for Research and Technology, Sixth Floor, Central University Organization, Corner of Ghods St., Keshavarz Boulevard, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1148956111

##### Phone

+98 21 6670 6142

##### Fax

##### Email

msahrai@tums.ac.ir

#### 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

Fatemeh Alsadat Hasheminasab Zavareh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

First Alley, Post Alley, 11 Khordad St., Mosalla Square

**City**

Zavareh

**Province**

Isfahan

**Postal code**

8441817716

**Phone**

+98 31 5437 6410

**Email**

fhz1373@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Alsadat Hasheminasab Zavareh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

First Alley, Post Coupe, 11 Khordad St., Mosalla Square

**City**

Zavareh

**Province**

Isfahan

**Postal code**

8441817716

**Phone**

+98 31 5437 6410

**Fax**

**Email**

f-hasheminasab@razi.tums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Alsadat Hasheminasab Zavareh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

First Alley, Post Coupe, 11 Khordad St., Mosalla Square

**City**

Zavareh

**Province**

Isfahan

**Postal code**

8441817716

**Phone**

+98 31 5437 6410

**Fax**

**Email**

f-hasheminasab@razi.tums.ac.ir

## 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**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available