

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effect of calf muscles dry needling on spasticity, knee and ankle range of motion and function in individuals with chronic stroke: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

Determine the effects of dry needling (DN) on spasticity, knee and ankle range of motion and function in individuals with chronic stroke

##### Design

A randomized, single-blind clinical trial with a parallel group design. The subjects are randomized with permuted block into two groups (interventional and control)

##### Settings and conduct

Subjects are recruited from individuals with chronic stroke who refer to Shiraz School of Rehabilitation Sciences. The study is single-blinded and the assessor of MMAS, knee and ankle ROM and TUG test outcome is unaware of subjects allocation to the groups

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 6 months after a stroke involving cerebral cortical regions. first-ever unilateral stroke. ankle dorsi flexor MMAS spasticity score  $\geq 2$ . able to ambulate without supportive device exclusion criteria: recurrent stroke. previous treatment with BTXA in the 6 months preceding the study. progressive or severe neurologic diseases, for example, heart conditions, unstable hypertension, fracture, or implants in the lower extremity. fear of needles. any contraindication for deep dry needling

##### Intervention groups

interventional group: rehabilitation exercises (strengthening exercise, PNF pattern and gait training), stretch of gastrocnemius, soleus and hip adductors muscles and DN over the gastrocnemius, soleus, tibialis anterior and hip adductors muscles on the spastic leg control group: rehabilitation exercises (strengthening exercise, PNF pattern and gait training) and stretch of gastrocnemius, soleus and hip adductors muscles

##### Main outcome variables

Modified Modified Ashworth Scale (MMAS); range of

motion (ROM); Timed up and go (TUG) test

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091130002793N5**

Registration date: **2019-09-10, 1398/06/19**

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

Last update: **2019-09-10, 1398/06/19**

Update count: **0**

##### Registration date

2019-09-10, 1398/06/19

##### Registrant information

##### Name

Shahla Zahednejad

##### Name of organization / entity

School Of Rehabilitation Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3102

##### Email address

snejad@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-09-18, 1398/06/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of calf muscles dry needling on spasticity, knee and ankle range of motion and function in individuals with chronic stroke: A Randomized Controlled Trial

**Public title**  
Effect of dry needling on spasticity in individuals with chronic stroke

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
6 months after a stroke involving cerebral cortical regions first-ever unilateral stroke ankle dorsi flexor MMAS spasticity score  $\geq 2$  able to ambulate without supportive device  
**Exclusion criteria:**  
recurrent stroke previous treatment with BTXA in the 6 months preceding the study progressive or severe neurologic diseases, for example, heart conditions, unstable hypertension, fracture, or implants in the lower extremity fear to needles any contraindication for deep dry needling

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: 40

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Permuted Block Randomization Randomization was achieved with an online randomization application to provide random permuted blocks with an block size of 4.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The assessor of MMAS, knee and ankle ROM and TUG test outcome was unaware of subjects allocation to the groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahwaz University of Medical Sciences

##### Street address

Ahwaz Jundishapour University of Medical Sciences, Golestan St, Ahwaz

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

7194714315

##### Approval date

2018-12-19, 1397/09/28

##### Ethics committee reference number

IR.AJUMS.REC.1397.812

## Health conditions studied

### 1

#### Description of health condition studied

spasticity, knee and ankle range of motion and function in individuals with chronic stroke

##### ICD-10 code

G81.1

##### ICD-10 code description

Spastic hemiplegia

## Primary outcomes

### 1

#### Description

spasticity

#### Timepoint

before intervention, 3 weeks after first session, immediately after last session and 1 week after last session

#### Method of measurement

Modified Modified Ashworth Scale

## Secondary outcomes

### 1

#### Description

knee range of motion

#### Timepoint

before intervention, 3 weeks after first session, immediately after last session and 1 week after last session

#### Method of measurement

protractor

## 2

### **Description**

ankle range of motion

### **Timepoint**

before intervention, 3 weeks after first session, immediately after last session and 1 week after last session

### **Method of measurement**

protractor

## 3

### **Description**

Functional activity

### **Timepoint**

before intervention, 3 weeks after first session, immediately after last session and 1 week after last session

### **Method of measurement**

Timed Up and Go test

## **Intervention groups**

### 1

#### **Description**

Intervention group: This group will receive rehabilitation exercises (strengthening exercises, PNF pattern and gait training) and stretch of gastrocnemius, soleus and hip adductors muscles for 6 weeks and 2 sessions in each week. Dry needling will apply over gastrocnemius, soleus, tibialis anterior and hip adductors muscles on the spastic leg if necessary.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: This group will receive rehabilitation exercises (strengthening exercises, PNF pattern and gait training) and stretch of gastrocnemius, soleus and hip adductors muscles for 6 weeks and 2 sessions in each week.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shiraz School of Rehabilitation Sciences

##### **Full name of responsible person**

Leila Abbasi

##### **Street address**

Abiverdi 1 St, Chamran Blvd, Shiraz

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7194733669

##### **Phone**

+98 71 3627 1551

##### **Email**

leabbasi@sums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Mohammad Badavi

##### **Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahwaz

##### **City**

Ahwaz

##### **Province**

Khuzestan

##### **Postal code**

1579461357

##### **Phone**

+98 61 3336 2414

##### **Email**

Badavi-m@ajums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Shahla Zahednejad

##### **Position**

Associate professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

Musculoskeletal Rehabilitation Research  
center, School Of Rehabilitation Sciences, Ahvaz  
Jundishapur

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

1579461357

**Phone**

+98 61 3374 3102

**Fax**

+98 61 3374 3506

**Email**

snejad@ajums.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shahla Zahednejad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Musculoskeletal Rehabilitation Research  
center, School Of Rehabilitation Sciences, Ahvaz  
Jundishapur

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

1579461357

**Phone**

+98 61 3374 3102

**Fax**

+98 61 3374 3506

**Email**

snejad@ajums.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shahla Zahednejad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Musculoskeletal Rehabilitation Research  
center, School Of Rehabilitation Sciences, Ahvaz  
Jundishapur

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

1579461357

**Phone**

+98 61 3374 3102

**Fax**

+98 61 3374 3506

**Email**

snejad@ajums.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**

The data of the participant alone is useless.

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

The results of primary outcomes will be shared.

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

two months after the publication of the results.

**To whom data/document is available**

academic researchers

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

Once accessed, individuals have the right to use the study protocol for rehabilitation purposes.

**From where data/document is obtainable**

Atousa Ebrahimi will be responsive through email.  
atousa192@yahoo.com

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

After receiving the request and mentioning the reasons for the request, the data will be answered within a maximum of one month.

**Comments**