

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

A study to investigate the effect of dry needling of forearm pronator muscles on spasticity and upper limb function in stroke patients

Protocol summary

Study aim

1- Determining the impact of spasticity of forearm pronator muscles on spasticity of other muscles and upper limb function in patients with chronic stroke. 2- If this method is effective, it is suggested to focus more on the treatment of pronators in improving spasticity and upper limb function.

Design

In this study, 20 patients are included in an easy and accessible way, and each patient will be considered as a control. In this cross-sectional study, all patients received sham needling in a three-session period, and then received dry needling in another three sessions with an interval of one week.

Settings and conduct

The intervention is carried out in the Faculty of Rehabilitation of Medical Sciences in Tehran. Each patient is considered as his own control. Patients receive dry needling or sham needling in separate sessions one week apart. Patients are not aware of the type of treatment. For each patient, the intervention will be carried out in two periods of three sessions

Participants/Inclusion and exclusion criteria

Age 40 to 75 years The first stroke that resulted in hemiplegia At least 6 months have passed since the stroke. The spasticity score of the forearm pronator muscles on the MMAS scale is equal to 1 or more. The supination range of the affected side should be at most 10% less than the healthy side. No history of dry needling intervention Not having cases of not using dry needling, such as fear of needles, receiving anticoagulants, infection, bleeding, or mental illness No treatment with botox or nerve blockers in the last 6 months Occurrence of any new lesion that affects muscle tone. Dissatisfaction to continue cooperation Taking any medicine that affects muscle tone

Intervention groups

Dry needling and Sham needling

Main outcome variables

severity of spasticity; active and passive range of motion; upper limb function; Function and Activities of daily living in the upper limb

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230721058873N1**

Registration date: **2023-09-22, 1402/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-22, 1402/06/31**

Update count: **0**

Registration date

2023-09-22, 1402/06/31

Registrant information

Name

Amirhossein Parsaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 1320

Email address

amirhosseinparsaei1377pt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A study to investigate the effect of dry needling of forearm pronator muscles on spasticity and upper limb function in stroke patients

Public title
Investigating the effect of dry needling on spastic muscles

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 40 to 75 years The first stroke that resulted in hemiplegia At least 6 months have passed since the stroke. The spasticity score of the forearm pronator muscles on the MMAS scale is equal to 1 or more. The supination range of the affected side should be at most 10% less than the healthy side. No history of dry needling intervention Not having cases of not using dry needling, such as fear of needles, receiving anticoagulants, infection, bleeding, or mental illness No treatment with botox or nerve blockers in the last 6 months
Exclusion criteria:
 Occurrence of any new lesion that affects muscle tone. Dissatisfaction to continue cooperation Taking any medicine that affects muscle tone

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
 Single blinded
Blinding description
 Dry needling and sham needling are used in this study. that each patient will be considered as his own control. Patients receive sham needling in a three-session period and dry needling in another three-session period. But patients are blinded regarding the use of sham needles.

Placebo
Used

Assignment
Crossover

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

North Kargar St., in front of Farshi Moghadam St., Tehran University of Medical Sciences dormitory complex

City

Tehran

Province

Tehran

Postal code

1439957181

Approval date

2023-09-03, 1402/06/12

Ethics committee reference number

IR.TUMS.FNM.REC.1402.126

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G81.10

ICD-10 code description

Spastic hemiplegia affecting unspecified side

Primary outcomes

1

Description

spasticity degree

Timepoint

Before the first session and after the third session of Sham needling and dry needling and one week after the third session of dry needling

Method of measurement

With physical examination based on the MMAS scale

Secondary outcomes

1

Description

Active and Passive range of motion

Timepoint

Before the first session and after the third session of Sham needling and dry needling and one week after the third session of dry needling

Method of measurement

goniometry

2

Description

upper extremity function

Timepoint

Before the first session and after the third session of Sham needling and dry needling and one week after the third session of dry needling

Method of measurement

Physical examination based on Brunnstrom's recovery stage

3

Description

Function and daily life activities of daily living in the upper limb

Timepoint

Before the first session and after the third session of Sham needling and dry needling and one week after the third session of dry needling

Method of measurement

Physical examination and based on the CAHAI 13 scale

Intervention groups

1

Description

Intervention group: Dry needling, Dry needling with the Fast in/Fast out technique and in a conical shape for 1 minute is applied to the pronator teres and pronator quadratus muscles at the motor points of these muscles.

Category

Rehabilitation

2

Description

Control group: Sham needling, With the same dry needling protocol, the patient feels the sharpness of the needle on the skin without piercing the patient's skin.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Nouredin Nakhostin Ansari

Street address

Faculty of Rehabilitation, corner of Safi Alishah St., Pich Shamiran St., Tehran

City

Tehran

Province

Tehran

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65111-11489

Phone

+98 21 7753 3939

Email

rehabilitation@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Tehran University of Medical Sciences
Headquarters, Qods Corner, Keshavarz Blvd.

City

Tehran

Province

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Postal code

1417653761

Phone

+98 21 8889 6696

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tumspr@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

Amirhossein Parsaei

Position

master of science student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Tehran University of Medical Sciences dormitory

complex, in front of Farshi Moghadam St., North Kargar St.

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Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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