

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

MOHAMMAD ALI SAHRAIAN

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

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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

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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