

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the short term effects of wrist flexor dry needling versus LI4 & TE5 acupuncture points dry needling on upper limb spasticity and function, in stroke patients: A Double-Blinded Randomized Clinical Trial

Protocol summary

Study aim

To determine the most effective and stable Dry Needling (DN) technique among LI4 & TE5 acupoints DN or wrist flexor DN, for Spasticity and function of stroke patients.

Design

A randomized, double-blinded clinical trial with a parallel group design of 20 patients.

Settings and conduct

Stroke patients are recruited through the physiotherapy centers. Demographic data and outcome variables are recorded at first session. Blinding is performed on patients, examiners and performers. The patient is not aware of the type of treatment group. Examiner is not aware of the treatment method, the allocation and DN is performed by a blinded-researcher to the examination results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age ≥ 18 years old, First-ever stroke, Disease duration of at least six months, Wrist flexor MMAS spasticity score ≥ 1 , Active and passive ROM of the involved wrist is at most 10% less than the non-involved side. Exclusion criteria: Diabetes, Inability to follow the therapist's instructions, Have contraindications to DN, Have participation simultaneously in another clinical trial, Have injections with BTXA in the 6 months preceding the study, Taking antispastic drug

Intervention groups

Intervention group 1: the needle applies in two acupoints of forearm and hand, including LI4 and TE5. "Intervention group 2: the DN is performed at the motor points of flexor carpi radialis and flexor carpi ulnaris muscles. The intervention used is DN, in which the acupuncture needle is inserted deeply into a point in the soft tissue without injecting any substance for one minute for each point. The needle is moved in different directions to the surface and depth of the tissue. The number of treatment sessions is three sessions during a week.

Main outcome variables

Spasticity (Modified Modified Ashworth Scale); motor function (Fugl-Meyer assessment); Active/Passive Range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200913048706N1**
Registration date: **2021-01-14, 1399/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-14, 1399/10/25**

Update count: **0**

Registration date

2021-01-14, 1399/10/25

Registrant information

Name

Najmeh Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3433 2429

Email address

najmeh_nazari@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-26, 1399/08/05

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the short term effects of wrist flexor dry needling versus LI4 & TE5 acupuncture points dry needling on upper limb spasticity and function, in stroke patients: A Double-Blinded Randomized Clinical Trial

Public title
The effect of dry needling technique on spasticity and function in stroke patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥ 18 years old First-ever stroke resulted in hemiplegia Disease duration of at least six months Wrist flexor Modified Modified Ashworth Scale (MMAS) spasticity score ≥ 1 Active and passive range of motion of the involved wrist is at most 10% less than the non-involved side

Exclusion criteria:
Have neurological disorders or diabetes Inability to follow the therapist's instructions Have contraindications to Dry Needling Have participation simultaneously in another clinical trial Have injections with botulinum toxin in the 6 months preceding the study Taking antispastic drug

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the number of patients in each group, the particular sort of treatment, either "wrist flexor dry needling" or "LI4&TE5 acupuncture points dry needling," is written on a piece of paper, and the paper is placed in Opaque sealed envelopes. The envelopes are then mixed. At the first visit session of each individual, the therapist who will not be involved in outcomes assessment will randomly select one of the envelopes. Based on the written sort of treatment specified, the therapist will do the patient's particular treatment. If any of the patients, for any reason, is omitted from the study, one envelope with the particular topic will be added again by the examiner, and they will be mixed again.

Blinding (investigator's opinion)
Double blinded

Blinding description

Although at first, the necessary explanation about the aims of the project and the existence of two groups are given to the patients, no explanation is given to them about the difference between the treatment methods. Besides, the patient's treatment sessions will be arranged so that the two groups' patients have no contact with each other and are not aware of the other group's treatment method. In this way, patients are blind regarding the treatment method. In addition, the allocation of participants into each of the treatment groups will be done by the therapist who performed the DN, and their clinical evaluation will be performed by another examiner who is not aware of the treatment group. So the examiner also is blind to the specific treatment method of each participant.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Nursing and Midwifery & Rehabilitation Schools- Tehran University of Medical Sci

Street address

Quds Ave., Keshavarz Blvd,

City

Tehran

Province

Tehran

Postal code

2181455618

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.TUMS.FNM.REC.1399.123

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G46.3

ICD-10 code description

Brain stem stroke syndrome

Primary outcomes

1

Description

Spasticity

Timepoint

Before intervention, immediately after intervention, and one week after intervention

Method of measurement

Modified Modified Ashworth Scale

2

Description

Function

Timepoint

Before intervention, immediately after intervention, and one week after intervention

Method of measurement

Fugl-Meyer assessment

Secondary outcomes

1

Description

Active Range Of Motion(ROM)

Timepoint

Before intervention, immediately after intervention, and one week after intervention

Method of measurement

Goniometer

2

Description

Passive Range Of Motion(ROM)

Timepoint

Before intervention, immediately after intervention, and one week after intervention

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group 1: wrist flexor dry needling including flexor carpi ulnaris and flexor carpi radialis in supine position and forearm in supination with filiform needles. The technique is done in the Fast in - Fast out method for one minute for each muscle / point. The number of treatment sessions is three sessions during a week.

Category

Rehabilitation

2

Description

Intervention group 2: LI4 & TE5 acupuncture points dry needling in supine position and forearm in pronation with filiform needles. The technique is done in the Fast in - Fast out method for one minute for each muscle / point.

The number of treatment sessions is three sessions during a week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurological physiotherapy Clinic, School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Najmeh Nazari

Street address

Department of physiotherapy, School of Rehabilitation., Pich.e.Shemiran., Enghelab St.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 3939

Fax

+98 21 7753 4133

Email

Najmeh_Nazari@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahrayan

Street address

Vice Chancellor for Research and Technology, Tehran University of Medical Sciences and Health Services, 6th Floor, Central University Organization, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

Email

vcr@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
Najmeh Nazari
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Physiotherapy Department, School of Rehabilitation,
Pich-e-Shemiran., Enghelab St.
City
Tehran
Province
Tehran
Postal code
11489-65111
Phone
+98 21 7753 5132
Fax
+98 21 7772 7009
Email
Najmeh_Nazari@outlook.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Najmeh Nazari
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Physiotherapy Department, School of Rehabilitation,
Pich-e-Shemiran., Enghelab St
City
Tehran
Province

Tehran
Postal code
11489-65111
Phone
+98 21 7753 5132
Email
Najmeh_Nazari@outlook.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Najmeh Nazari
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Physiotherapy Department, School of Rehabilitation,
Pich-e-Shemiran., Enghelab St.
City
Tehran
Province
Tehran
Postal code
11489-65111
Phone
+98 21 7753 5132
Fax
+98 21 7772 7009
Email
Najmeh_Nazari@outlook.com

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 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 available only to other researchers to study and evaluate treatment outcomes.

From where data/document is obtainable

By sending an email to the corresponding author.

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

Sending an Email to the corresponding author and request the data.

Comments