

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effectiveness of Dry Needling on Upper and Lower Dysfunction on stroke patients

Protocol summary

Study aim

The Effect of Dry Needling on Upper and Lower Limb Dysfunction of Stroke Patients

Design

Double blind, sham controlled, randomized

Settings and conduct

A randomized clinical trial was conducted on 24 patients with a stroke who had been identified with a definitive diagnosis in Imam Khomeini Hospital and had hemiplegia. Patients are randomly selected randomly in one of the two intervention groups and the control group based on entry criteria and consent to participate in the research.

Participants/Inclusion and exclusion criteria

18-75 years; first brain stroke; Sufficient communication skills to show yes / no verbally or through gestures; be able to walk for at least 10 meter; unilateral hemiparesis.

Intervention groups

A specialist who has expertise in dry needling, will deliver three sessions of dry needling on the flexor carpiradialis and flexor carpiulnaris muscles of the upper extremity and gastrocnemius muscle of the lower extremity on the affected side the intervention group. Evaluation the effect of dry needling on the spasticity of aforementioned muscles on the affected side will do immediately after last session of dry needling and after 1 month of baseline, in comparison with baseline information gained before doing dry needling in the intervention group. All these procedures will do for control group but using placebo dry needling instead of dry needling for control group.

Main outcome variables

spasticity (MMAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171111037388N4**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **retrospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Ardalan Shariat

Name of organization / entity

TUMS

Country

Iran (Islamic Republic of)

Phone

+98 939 861 4772

Email address

a-shariat@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-01, 1397/03/11

Expected recruitment end date

2019-02-01, 1397/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Dry Needling on Upper and Lower Dysfunction on stroke patients

Public title

The Effectiveness of Dry Needling on Spasticity

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 first brain stroke Sufficient communication skills to show yes / no verbally or through gestures be able to walk for at least 10 meter MMAS score equal or more than one unilateral hemiparesis
Exclusion criteria:
 unable patients to follow the instructions severe musculoskeletal disorders (For example, severe osteoporosis, arthritis} psychiatric disorders requiring drug therapy cognitive disorders contraindication to dry needling using anti-spastic drugs

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the random number table, patients are placed in one of two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are not aware of being in the intervention group or the control group. The control group will receive the intervention once the study finished. In addition, both group participate in their conventional therapies. Measurements are performed by an assessor who does not know the training protocols that each group has done.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

committee Ethics Committee of Tehran University of Medical Sciences

Street address

No 7, Al-e-Ahmad Highway, Tehran, IR Iran

City

Tehran

Province

Tehran

Postal code

14395-578

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.TUMS.VCR.REC.1397.721

Health conditions studied

1

Description of health condition studied

Brain Stroke

ICD-10 code

164

ICD-10 code description

Stroke, not specified as hemorrhage or infarction

Primary outcomes

1

Description

Walking speed

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

10 meter walking test

2

Description

spasticity

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

modified modified ashworth scale

3

Description

mobility

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

Timed up and go test

4

Description

hand dexterity

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

Box and Block test

Secondary outcomes

1

Description

Balance

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

Single Leg Stance Test

2

Description

Daily living activity

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

Barthel index

3

Description

range of motion

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

goniometer

4

Description

pennation angle of gastrocnemius muscle

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

sonography

5

Description

gastrocnemius muscle thickness

Timepoint

Baseline, immediately after treatment and after 4 weeks

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: A specialist who has expertise in dry needling, will deliver three sessions of dry needling on the spastic muscles of the upper and lower extremities on the hemiplegic side with a 48 hours interval between sessions. At baseline, immediately after last session of dry needling and after 1 month of baseline, the blind assessor, expert physiotherapist, will perform the clinical tests.

Category

Treatment - Devices

2

Description

Control group: A specialist who has expertise in dry needling, will deliver three sessions of placebo dry needling on the spastic muscles of the upper and lower extremities on the hemiplegic side with a 48 hours interval between sessions. At baseline, immediately after last session of placebo dry needling and after 1 month of baseline, the blind assessor, expert physiotherapist, will perform the clinical tests.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Prof.Noureddin Nakhostin Ansari

Street address

Gharib Ave, Keshavarz blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi, Research Vice-Dept. of Neuro Res Cen,
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Grant name

Research Vice-Dept. of Neuroscience Research Center,
Tehran University of Medical Sciences

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

Ardalan Shariat

Position

Post doctoral Fellow

Latest degree

Ph.D.

Other areas of specialty/work

Neurorehabilitation

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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

No more data

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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

All the data will be shared after removing identification details of participants. We will publish the results as a scientific article without any name from participants.

When the data will become available and for how long

After finish the protocol, the article will be published and will be available permanently.

To whom data/document is available

data is only available for people working in academic institutions

Under which criteria data/document could be used

For academic purpose

From where data/document is obtainable

Ardalansh2002@gmail.com Dr.Ardalan Shariat

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

Call to the corresponding author directly

Comments