Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Ardalan Shariat

Name of organization / entity
TUMS

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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
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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