Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison on the effects of a single session of brachialis and Flexor Carpi Radialis muscles' dry needling on spasticity and brain activities of patients after stroke based on fMRI findings.

Protocol summary

Study aim

Determining the effectiveness of upper extremity dry needling in stroke patients. CNS changes comparison of dry needling of the brachialis and flexor carpi radialis muscles, as well as the comparison of the effect of distal muscle dry needling on the spasticity of the proximal muscle and the active/passive range of motion of the proximal joint and vice versa.

Design

A controlled, parallel-group, single-blind, clinical trial which randomized by computerized numbering and numbered sealed envelopes on 20 stroke patients.

Settings and conduct

Coordinating with the National Brain Mapping Lab(NBML) and presenting an outline of the research and conducting initial discussions with the supervisor and also the fMRI unit expert. Then making a deal with NBML and determining the time for the presence of researcher and patients to perform the intervention and data registration of brain activities, spasticity and active/passive range of motion of the wrist and elbow.

Participants/Inclusion and exclusion criteria

Middle-aged stroke patients, with hemiplegia of one half of the body, who have upper limb spasticity (at least score>=1 in the MMAS test) and have at least possible mental and physical ability to participate in the study, as well as dry needling treatment method and f-MRI diagnostic method will not be harmful for them.

Intervention groups

In this study there are two groups which both of them receive dry needling intervention. with the difference that one group undergoes dry needling in the brachialis muscle (as a proximal muscle) and the other group in the flexor carpi radialis muscle (as a distal muscle). In this situation, the control group becomes active, that is, each group while receiving the intervention is considered as the control of the other group.

Main outcome variables

Severity of spasticity (evaluated using the MMAS test)
Brain activity intensity (number of active voxels)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230123057192N1**
Registration date: **2023-02-14, 1401/11/25**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Mahdi Seyfollahipoor

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-01, 1401/12/10

Expected recruitment end date

2023-05-15, 1402/02/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison on the effects of a single session of brachialis and Flexor Carpi Radialis muscles' dry needling on spasticity and brain activities of patients after stroke based on fMRI findings.

Public title
Effects of dry needling as a physiotherapy approach on brain activities and spasticity of patients after stroke.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
First ever stroke resulted in hemiplegia Age between 40 to 65 years MMAS Score of spasticity in related muscles should be at least 1
Exclusion criteria:
Previous treatment with nerve blocks, motor point injection with neurolytic agents for spasticity at any time, or with BTX-A in the 6 months preceding the study Existence of severe Cognitive and perceptual deficits History of dry needling in the past 6 months Contraindications to dry needling Cervical radiculopathy Contracture of related muscles Unwilling to take part in the study Contraindications to MRI
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Concealed allocation by using a computer-generated randomised table of numbers created before data collection and then delivery of the secret sealed envelopes which include numbered cards. The therapist opens the envelope and performs the treatment according to the specified group.
Blinding (investigator's opinion)
Single blinded
Blinding description
f-MRI unit expert as the first evaluator (collector of brain activity variable data) and also a physiotherapist as the second evaluator (collector of other variable data) in this research are blind to the treatment groups . In this way, both people only collect the data presented by the main researcher without knowing about the treatment and the related treatment group.
Placebo
Not used
Assignment
Parallel
Other design features
In this study, both groups will be treated by dry needling, with the difference that the intervention for one group is for the brachialis muscle (as the proximal muscle) and in the other group for the flexor carpi radialis muscle (as the distal muscle).In this case, we have active control group, it means that each group receiving the intervention should be considered as a control for the other group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
Central Organization of Tehran University of Medical Sciences, corner of Qods St., Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
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Approval date
2023-01-18, 1401/10/28
Ethics committee reference number
IR.TUMS.FNM.REC.1401.140

Health conditions studied

1

Description of health condition studied
Stroke, Hemiplegia, spasticity
ICD-10 code
G81.1
ICD-10 code description
Spastic hemiplegia

Primary outcomes

1

Description
The severity of spasticity of the brachialis and flexor carpi radialis muscles, which is measured based on the MMAS test.
Timepoint
Before, immediately after and 30 minutes after the intervention
Method of measurement
Through the MMAS test by a physiotherapist who is

expert in patients with hemiplegia

2

Description
Severity of brain activity
Timepoint
Before, immediately after and 30 minutes after the intervention
Method of measurement
Analysis of fMRI findings after finger tapping

Secondary outcomes

1

Description
Active/passive elbow and wrist range of motions
Timepoint
Before, immediately after and 30 minutes after the intervention
Method of measurement
Through a goniometer and by a physiotherapist familiar with the desired assessment

Intervention groups

1

Description
Intervention group: Deep fast in and fast out method of dry needling in the brachialis muscle for 1 minute.
Category
Rehabilitation

2

Description
Intervention group: Deep fast in and fast out method of dry needling in the flexor carpi radialis muscle for 1 minute.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences
Full name of responsible person
Seyed Mohsen Mir
Street address
School of rehabilitation of Tehran University of Medical Sciences, corner of Safi Alishah Ave., Piche shemiran, Enghelab Ave.
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Sponsors / Funding sources

1

Sponsor
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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
Mahdi Seyfollahipoor
Position
Student , Master of Science
Latest degree

Bachelor
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Person responsible for updating data

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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 the 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 only available to other researchers to study and evaluate treatment outcomes.
From where data/document is obtainable
Dr. Noureddin Nakhostin Ansari, Department of Physiotherapy, School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran, 09122979309, nakhostin@sina.tums.ac.ir
What processes are involved for a request to access data/document
By sending an official E-mail to the corresponding author, professor Noureddin Nakhostin Ansari(nakhostin@sina.tums.ac.ir) and request the data. The researcher will be answered as soon as possible
Comments