Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

Effects of Dry Needling and Exercise Therapy on Post-Stroke Spasticity and Motor Function– A Randomized Clinical Trial

Protocol summary

Study aim

The purpose of this study was to compare the effect of dry needle with and without exercise therapy on wrist flexor spasticity, motor function and motor neuron excitability in patients with chronic stroke.

Design

A single-blind randomized clinical trial with parallel groups and three-week follow-up. Randomization will be done by selecting the opaque envelopes. The sample size was 12 patients in each group according to the results of similar studies using G power software.

Settings and conduct

Patients who meet the inclusion criteria will be recalled from neurosurgery clinics. After initial evaluations, patients will be randomly assigned to the control and treatment groups by selecting the opaque envelopes by the secretary of the clinic . The treatment group will receive the dry needle with the exercise therapy and the control group only receive the dry needle. Treatment will be performed once a week for 4 weeks and assessments are performed again after 4 weeks as well as after a 3-week follow-up. One experienced physiotherapist will perform the assessments and the other will perform the evaluation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Documented diagnosis of stroke by a neurologist; At least 6 months have passed since the stroke; Age over 40 years; being the first time stroke leading to hemiplegia; Spasticity greater than one for wrist flexor muscles based on the MMAS scale. Exclusion criteria: Having contracture in hand; Contraindication for dry needling

Intervention groups

Intervention group: Dry needling with exercise therapy. 4 sessions exercise therapy after dry needle (onse a week)
Control group: Dry needling. 4 sessions dry neddling (once a week)

Main outcome variables

Wrist flexor spasticity; motor neuron excitability; motor function; wrist extension range of motion

General information

Reason for update

Due to the exercise therapy intervention, blinding patients will not be feasible in this study. Therefore, the blind section and the title of the study were edited and modified.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180611040061N1**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**
Update count: **4**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name
Seyedeh Saeideh Babazadeh-Zavieh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-20, 1399/08/30

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Dry Needling and Exercise Therapy on Post-Stroke Spasticity and Motor Function– A Randomized Clinical Trial

Public title

Effect of dry needling with exercise therapy on stroke spasticity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Documented diagnosis of stroke by a neurologist At least 6 months have passed since the stroke Age>40 years Being the first time stroke leading to hemiplegia Spasticity greater than one for wrist flexor muscles based on MMAS scale Absence of sensory disorders, bleeding, upper limb malignancies, ulcers and infection Ability to understand therapist and evaluator instructions Full consent to participate in the research

Exclusion criteria:

Fear of applying dry needles Having contracture in hand Contraindication for dry needling Other neurological lesions Having Diabetes Any history of treatment with nerve blockers such as botulinum toxin A 6 months prior to inclusion

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign the patients, the opaque envelopes will be prepared containing the assigned terms "dry needling" or "dry needling+ exercise therapy" interventions. The secretary of the clinic will be choosing an envelope randomly.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single-blind clinical trial in which a expert physiotherapist will perform intervention and other physiotherapists will perform the Assessment. As a result, the Assessor will not know which group the patient belongs to.

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

School of Rehabilitation Sciences, Enghelab Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.TUMS.FNM.REC.1399.008

Health conditions studied

1

Description of health condition studied

Chronic stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Wrist flexors spasticity

Timepoint

Measurement of Spasticity before and after the intervention (4 weeks after intervention) and 3 weeks after the intervention

Method of measurement

Persian version of Modified Modified Ashworth Scale

2

Description

Alpha motor neuron excitability

Timepoint

Before and after intervention (4 weeks after intervention) and 3 weeks after intervention

Method of measurement

Electromyography machine (EMG)

Secondary outcomes

1

Description
Range of motion
Timepoint
Before and after intervention (4 weeks after intervention) and 3 weeks after intervention
Method of measurement
Goniometer

2

Description
Motor function
Timepoint
Before and after intervention (4 weeks after intervention) and 3 weeks after intervention
Method of measurement
Study of patients motor function with Fugl-Meyer Scale and Action Research Arm Test

Intervention groups

1

Description
Intervention group: In the treatment group, patients will receive exercise therapy in addition to dry needle. Immediately after dry needle, patients will do exercises in Structure, Function, and Activity levels to mobilize wrist and finger joints to relieve muscle strength imbalance and gain motor control of affected limb and improve performance for 30 to 45 minutes, once a week, for a total of 4 weeks. The same exercises will be performed once a day at home and if they are unable to fully perform each exercise, the therapist in the clinic and a person at home will help the patients.
Category
Rehabilitation

2

Description
Control group: The control group will only receive dry needle intervention. Dry needle treatment will be administered once a week for 4 weeks. Patients in this group will continue their previous activities throughout life without any changes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Yahyaian hospital
Full name of responsible person
Seyed Abbas Motavalian
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Shafa Yahyaian hospital, Mojahedin-e-Islami Street, Baharestan Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohsen Hashemi Sanjani
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Sixth Floor, Central Organization of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.
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Web page address
http://rmo.tums.ac.ir/index.jsp?fkeyid=&siteid=39&pageid=5658
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
Nastaran Ghotbi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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
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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
If needed by researchers and their request, the raw data of research and it's analysis will be available to researchers

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
Email the corresponding author and request the data

Comments