Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of dry needling on elbow flexor spasticity and corticospinal excitability in patients with chronic stroke: A double-blind, randomized, controlled trial

Protocol summary

Study aim
evaluating the impact of dry needling on the corticospinal tract's excitability and spasticity in individuals with chronic stroke

Design
Clinical experiment on 30 patients, double-blinded, randomized, with a sham control group, Blocked-balance randomization was used for randomization

Settings and conduct
Patients are invited to Firouzgar Hospital for research, where they fill out informed consent forms. Baseline patient information such as age, sex, height, weight, duration, and side of affliction is recorded. Clinical assessments are performed, and patients are then divided into dry needling or sham needling treatment groups via block-balanced randomization. They receive their respective treatments over two more sessions, with follow-up evaluations after at least a week. Assessments include the MMAS spasticity scale, passive elbow resistance, active and passive elbow range of motion, and corticospinal tract excitability. The patient, healthcare provider, and evaluator are all blinded.

Participants/Inclusion and exclusion criteria
inclusion criteria: chronic stroke-related hemiplegia The MMAS scale indicates that the elbow flexor muscles on the afflicted side have spasticity that is at least 1 in severity. Age 30-75 Ability to follow instructions Criteria for not participating in the study: receiving alternative treatments Medication to reduce spasticity restricting TMS use

Intervention groups
The patient is placed in a supine position, head on the pillow, elbows flexed, and forearms supinated. Alcohol cleans the front arm skin. The dry needling group receives needles for the biceps brachialis and brachialis muscles for one minute using a sterile 0.3 x 0.5 needle and the Fast-in and Fast-out conical technique. The control group receives a placebo needle. Patients receive three sessions every other day.

Main outcome variables
Corticospinal tract excitability, Spasticity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230708058719N1**
Registration date: **2023-08-02, 1402/05/11**
Registration timing: **prospective**

Last update: **2023-08-02, 1402/05/11**
Update count: **0**

Registration date
2023-08-02, 1402/05/11

Registrant information

Name
Shiva Komesh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-01, 1402/06/10

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dry needling on elbow flexor spasticity and corticospinal excitability in patients with chronic stroke: A double-blind, randomized, controlled trial

Public title

Effect of Dry needling on decreasing elbow flexor stiffness in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

stroke-induced hemiplegia A minimum of six months have passed since the occurrence of the stroke, indicating a chronic stage of the disease. The degree of spasticity exhibited by the elbow flexor muscles on the affected side, as determined by the Modified Modified Ashworth Scale (MMAS), is a minimum of 1. Age 30-75 Ability to follow instructions

Exclusion criteria:

Individuals undergoing other treatments to alleviate spasticity The administration of pharmacological interventions aimed at reducing spasticity Not having any contraindications to using the TMS device, such as a history of seizures, epilepsy (the person themselves or a first-degree family member), a history of head injury or brain injury, metal in the head (outside the mouth) such as surgical clips, cochlear implants, or welded parts, a history of negative reactions to MRI or TMS, a history of brain-related diseases such as MS or brain tumors, a history of fainting, or a history of severe headaches,pregnancy or conception intention within the last three months, Past use of drugs known to reduce the seizure threshold, such as imipramine, amitriptyline, doxepin, nortriptyline, maprotiline, chlorpromazine, clozapine, foscarnet, ganciclovir, ritonavir, theophylline, phenytidine, ketamine, gamma hydroxybutyrate, amphetamine, cocaine, and recent use of drugs or alcohol

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block-Balanced Randomization:In this study, block balanced randomization is used to ensure that participants are allocated equally to each group. In order to maintain balance throughout the experiment, each block has an equal amount of each intervention, randomly assigned in unpredictable orders.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study used a double-blind randomized controlled trial design, wherein one proficient physiotherapist administers the treatments, while another physiotherapist conducts the assessments. Consequently, the evaluator lacks knowledge regarding the patient's group status, and the patients themselves remain unaware of their respective group assignments

Placebo

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

2023-06-19, 1402/03/29

Ethics committee reference number

IR.TUMS.FNM.REC.1402.063

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
Corticospinal excitability
Timepoint
prior to the commencement of the intervention, after three sessions of the intervention, and one week subsequent to the intervention.
Method of measurement
The transcranial magnetic stimulation device is utilized to measure the resting motor threshold in elbow flexor muscles while simultaneously recording the corresponding motor-evoked potential via electromyography

2

Description
Spasticity of the elbow flexor muscles
Timepoint
prior to the commencement of the intervention, after three sessions of the intervention, and one week subsequent to the intervention
Method of measurement
Modified Modified Ashworth Scale

Secondary outcomes

1

Description
The active and passive range of motion of the elbow joint
Timepoint
prior to the commencement of the intervention, after three sessions of the intervention, and one week subsequent to the intervention
Method of measurement
The assessment will be conducted utilizing a goniometry

2

Description
Passive resistance force
Timepoint
prior to the commencement of the intervention, after three sessions of the intervention, and one week subsequent to the intervention
Method of measurement
the hand-held dynamometer

Intervention groups

1

Description
Intervention group: In order to execute the intervention, the patient assumes a supine position. The head is positioned upon the pillow, aligned with the midline. The arms are slightly abducted, with the elbows slightly flexed and the forearms in a supinated position. The anterior aspect of the arm is sterilized using alcohol. Subsequently, within the dry needling group a sterile needle measuring 0.3 x 0.5 is employed by the Fast-in and Fast-out conical technique to administer needling to the biceps brachialis and brachialis muscles for a duration of one minute. The biceps brachii and brachialis muscles are penetrated at a distance of 2 centimeters out of the point where the upper three-fourths and lower one-fourth of the line connecting the coracoid process to the medial epicondyle of the humerus intersect.
Category
Rehabilitation

2

Description
Control group: instead of dry needles, sham needles will be employed to target the same muscle groups as previously mentioned. Sham needles have a relatively wide edge that solely induces skin irritation without penetrating the dermal layer.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Bijan Forough
Street address
Firoozgar Hospital, Beh Afarin St., Karim Khan Zand Blvd., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
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Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
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Master

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
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 and analysis of the research will be made available to researchers upon their request, should it be deemed necessary by the researchers

When the data will become available and for how long

Following the publication of the articles derived from the conducted research

To whom data/document is available

Scholars conducting research within academic establishments

Under which criteria data/document could be used

The data is exclusively accessible to fellow researchers for the purpose of studying and evaluating treatment outcomes

From where data/document is obtainable

by contacting the corresponding author through email

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

Send an email to the responsible author and request the document

Comments