

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect Of Dry Needling on Spasticity, consistency of Corticospinal Tract and Function of Upper Extremity In Subject with Stroke

Protocol summary

Study aim

Determine to effect of dry needling on spasticity, consistency of corticospinal tract and function of upper extremity in subjects with stroke.

Design

A clinical trial, double-blind, placebo-controlled clinical trial will be performed using sample of convenience and sample size of 10 individuals in each group.

Settings and conduct

Dry needling will be performed using a sterilized, stainless, disposable nipple with a size of 0.25 mm 0.30 mm. Patients are in supine position, the arm is far from the trunk and elbow in supination. The technique used is fast in-fast out for each muscle for one minute.

Participants/Inclusion and exclusion criteria

Patients who 1) at least six month have passed since their stroke 2) have had only one stroke 3) MMAS test is one to three, 3) Did not use any anti-spasticity medication 24 hours before of intervention will be included. People with dry needle contraindications, or any other neurological disease, or having a fixed muscle contraction in the wrist will be excluded.

Intervention groups

In the intervention group (Dry needling): Wrist flexor muscles (flexor carpi ulnaris and flexor carpi radialis) were considered for needling. So patients undergo 3 sessions (every other day) deep needling for the affected wrist flexor muscles. In control group(sham dry needling), Instead of dry needles, sham needles will be used for the same muscles as above. Sham needle has a thick edge that without irritating the skin only stimulates the skin.

Main outcome variables

The outcome measures include severity of spasticity by MMAS will be measured, consistency of CST which evaluated by DTI) and hand dexterity which will be measured by BBT), and active and passive ROM that will be assessed by goniometer) before and after of treatment in both groups.

General information

Reason for update

Unfortunately, due to the corona pandemic, the start of data collecting of patient was delayed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045649N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**

Update count: **2**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Masoome Ebrahimzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Dry Needling on Spasticity, consistency of Corticospinal Tract and Function of Upper Extremity In Subject with Stroke

Public title

Effect Of Dry Needling on Spasticity, consistency of Corticospinal Tract and Function of Upper Extremity In Subject with Stroke

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

disease duration of at least six months first ever stroke wrist flexor MMAS spasticity score 1 up to 3 Taking no antispastic drug 24 hour before of the entrance to study

Exclusion criteria:

contraindications to Dry Needling presence of any other neurological disorder Fixed muscle contractures at the wrist joint

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 106

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into intervention or control groups according to the stratified permuted block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Treatment will be performed by a trained therapist. The evaluation is performed by another physiotherapist who is unaware of the grouping and treatment process of the patients. Patients will also be unaware of the grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar dead, Daneshjoo Boulevard , Evin,

City

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Province

Tehran

Postal code

1985713834

Approval date

2019-11-24, 1398/09/03

Ethics committee reference number

IR.USWR.REC.1398.149

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Consistency corticospinal tract by fractional anisotropy value severity of spasticity

Timepoint

One day before the intervention and one day after the third intervention session

Method of measurement

Corticospinal tract imaging device OR Difussion tensor imaging MMAS

Secondary outcomes

1

Description

Wrist active ROM EXT Dexterity of hand

Timepoint

One day before intervention and on day after end of intervention

Method of measurement

Goniometer

2

Description

Wrist passive ROM EXT

Timepoint

One day before intervention and on day after end of intervention

Method of measurement

Goniometer

3

Description

Hand dexterity

Timepoint

One day before intervention and on day after end of intervention

Method of measurement

Box and Block test

Intervention groups

1

Description

Intervention group: The study included wrist flexor muscles (carpal ulnaris flexor and carpi radialis flexor). Patients underwent 3 sessions for (every other day) for deep wrist flexion of the affected wrist muscles. The technique used is fast in-fast out for each muscle for one minute.

Category

Rehabilitation

2

Description

Control group: Instead of dry needles, sham needles will be used for the same muscles as above. Sham needles have a thick edge that only irritates the skin without piercing the skin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

National Brain Mapping Lab

Full name of responsible person

Mohamadreza Ay

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South side of the Faculty of Electrical Engineering,Campus of Technical Schools,Kargar North Street,Tehran,Iran

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr M ohamadreza khodaei ardakani

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Second Floor, Farabi Building ,University of Social Welfare and Rehabilitation Sciences,Koodakyar Impasse,Daneshjoo Blvd, Evin,Tehran

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Masoome ebrahimzadeh

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

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

demographic data and primary and secondary outcome measures can be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

any use of data must be in coordination with authors

From where data/document is obtainable

Iraj Abdollahi Irajabdollahi@hotmail.com Masooome Ebrahimzadeh ,coworker
masooome.Ebrahimzadeh@gmail.com

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

a request must be sent to email address and if it will be approved , the files will be sent.

Comments