Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 stroke2) 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 measurerd), consistency of CST which evaluated by DTI) and hand dexterity which will 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 scienece

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
Tehran
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
https://nbml.ir/FA/pages/about

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
Street address
Second Floor,Farabi Building ,University of Social Welfare and Rehabilitation Sciences,Koodakyar Impasse,Daneshjoo Blvd, Evin,Tehran
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1985713834
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rd@uswr.ac.ir
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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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 out come 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 Abdolllahi Irajabdollahi@hotmail.com Masoome Ebrahimzadeh ,coworker masoome.Ebrahimzadeh@gmail.com

What processes are involved for a request to access data/document
a request must be send to email address and if it will be approved , the files will be send.

Comments