Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of two methods of dry needling application on spasticity, range of motion and upper limb function in patients with chronic stroke: a randomized clinical trial

Protocol summary

Study aim

Comparison and determination of the most effective method of dry needling application among two methods of fast in fast out and rotational needling on spasticity, range of motion and functional movement of upper limb of stroke patients.

Design

A randomized double blinded clinical trial with the parallel group design of 20 patients.

Settings and conduct

Patients are selected from the volunteers referring to the rehabilitation clinics of Tehran University of Medical Sciences by registering personal information and evaluating the outcome variables. Blindness is performed in patients, examiners and performers of the intervention. Patients are not aware of the difference in treatment techniques and the examiner is not aware of the treatment methods of patients. The performer of the intervention has no information about the results of the evaluations.

Participants/Inclusion and exclusion criteria

People with the first time stroke more than six months and age range of 18 to 75 years old. The degree of spasticity of their wrist based on a modified modified scale is equal or greater than one, they do not take antispam and do not receive other treatments. exclusion criteria: Any dry needling contraindication, cognitive problems, diabetes or neurological pain, fixed muscle contraction in the wrist and unwillingness to participate in the project.

Intervention groups

In one group the needles are used in fast in fast out cone shape technique during one minute in the wrist flexor muscles; in the second group, the needles are inserted to the target muscles and rotated to one side and will be remain for ten minutes and after 5 minutes, the torsion will be applied again. The number of treatment sessions will be three which are performed during a week.

Main outcome variables

Spasticity(Modified Modified Ashworth), Upper Limbe 's motor function(Fugl-Meyer), Wrist range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210713051875N1**
Registration date: **2021-08-02, 1400/05/11**
Registration timing: **prospective**

Last update: **2021-08-02, 1400/05/11**
Update count: **0**

Registration date

2021-08-02, 1400/05/11

Registrant information

Name

Roshanak Honarpisheh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7751 0174

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-11, 1400/05/20

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two methods of dry needling application on spasticity, range of motion and upper limb function in patients with chronic stroke: a randomized clinical trial

Public title

The effect of dry needle techniques in the treatment of upper limb patients with stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

first-ever stroke resulted in hemiplegia disease duration of at least 6 months wrist flexor modified modified Ashworth Scale (MMAS) spasticity score ≥1 No limitation in passive range of motion of the effected wrist

Exclusion criteria:

Any cognitive problems in the patient Diabetes or neurological pain Wrist contracture Dry needling contraindication Taking anti-Spastic drugs

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the number of patients in each group, the particular sort of treatment (fast in fast out or rotational manipulation techniques) is written on a piece of paper. Each paper is placed in a sealed envelope. One envelope will be chosen randomly by the therapist at the first session of the patient treatment and the patient's treatment technique is selected based on that. If any of the patients is omitted from the study, one envelope related to the excluded patient treatment group will be replaced and they will be mixed again.

Blinding (investigator's opinion)

Double blinded

Blinding description

At first, necessary explanation about the study, the aims and the existence of two groups are given to the patients; Whereas no information about the difference methods of treatments between two groups will be given to them. There will be no connection between patients of each groups. This way patients are blind regarding treatments methods. In addition examination will be preformed by a physiotherapist who is not aware of the treatment group. So examiner is blind to the treatment method of each participant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee OF Nursing and Midwifery & Rehabilitation schools- Tehran university of Medical Sc

Street address

Quds Ave, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

2181455618

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.TUMS.FNM.REC.1400.062

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G46.3

ICD-10 code description

Brain stem stroke syndrome

Primary outcomes

1

Description

Spasticity

Timepoint

Before intervention, immediately after intervention, one week after intervention

Method of measurement

Modified Modified Ashworth

2

Description

Function

Timepoint
Before intervention, immediately after intervention, one week after intervention
Method of measurement
Fugle-Meyer assessment upper extremity scale

Secondary outcomes

1

Description
Active wrist range of motion
Timepoint
Before intervention, immediately after intervention, one week after intervention
Method of measurement
Goniometer

2

Description
Passive wrist range of motion
Timepoint
Before intervention, immediately after intervention, one week after intervention
Method of measurement
Goniometer

Intervention groups

1

Description
Intervention group: Dry needling is performed by fast in fast out technique for the wrist flexor muscles, including the flexor carpi radialis and the flexor carpi ulnaris. Each needle is applied for one minute. The number of treatment sessions will be three sessions during a week.
Category
Rehabilitation

2

Description
Intervention group: Dry needling is used with the rotation technique on the flexor muscles of the wrist, including the flexor carpi radialis and flexor carpi ulnaris. The needle stays in this position for ten minutes and after five minutes the twist is extended again. The number of treatment sessions will be three sessions during a week.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurological physiotherapy clinic, School of rehabilitation, Tehran University of Medical Science
Full name of responsible person
Roshanak Honarpisheh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mohammed Ali Sahrayian
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Vice Chancellor for Research and Technology, Central Organization of Tehran University of Medical Sciences, 6th Floor, Ghods St., Keshavarz Blvd
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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
Roshanak Honarpisheh
Position
Ph.d candidate
Latest degree
Master
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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 of research and its analysis will be available to the researcher 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 institution
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
Department of physiotherapy, School of Rehabilitation, Enghelab St; Professor Soofia Naghdi Email address: naghdi@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 Soofia Naghdi (naghdi@sina.tums.ac.ir) and request the data. The researcher will be answered as soon as possible.
Comments