Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Effect of dry needling technique on clinical, sonographic and biomechanical parameters of spastic upper extremity muscles in patients with chronic ischemic stroke

Protocol summary

Study aim
Effect of dry needling technique on clinical, sonographic and biomechanical parameters of spastic upper extremity muscles in patients with chronic ischemic stroke

Design
This clinical trial has a sham control group, with parallel groups, double-blinded, and randomized by stratified permutation blocks method with block size 4. Statistical software is used for randomization.

Settings and conduct
Patients referred to medical centers of SUMS who suffer from chronic ischemic stroke with spastic muscles in their upper limbs, enter the study according to the inclusion and exclusion criteria. Then they will sign the informed consent. After that they are randomly assigned to intervention group (routine physiotherapy with dry needling) and control group (routine physiotherapy with sham dry needling). Treatment by a physiotherapist, assessments by another physiotherapist and statistical analysis by a statistician will be performed who are unaware of group assignment.

Participants/Inclusion and exclusion criteria
Patients with chronic ischemic stroke in the age range of 35-65 years are included in the study. At least six months and maximum 2 years must be passed since the onset of their stroke. They cannot participate in this study if they are receiving other treatments.

Intervention groups
The intervention group receives dry needling treatment with routine physiotherapy and the control group receives routine physiotherapy with sham dry needling.

Main outcome variables
Resistance to passive stretching (spasticity) in the wrist and fingers flexor muscles; Upper limb motor function; Upper limb skill; Thickness of the FCU, FCR and FDP.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200904048609N1**
Registration date: **2020-09-23, 1399/07/02**
Registration timing: **prospective**

Last update: **2020-09-23, 1399/07/02**
Update count: **0**
Registration date
2020-09-23, 1399/07/02

Registrant information
Name
Fatemeh Panahi
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
2020-11-14, 1399/08/24
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of dry needling technique on clinical, sonographic and biomechanical parameters of spastic upper extremity muscles in patients with chronic ischemic stroke

Public title
Effect of dry needling technique on spastic upper extremity muscles in patients with chronic ischemic stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 35-65 years old Stroke occurrence for first time History of stroke onset at least 6 months and maximum of 2 years prior to the study Spasticity existence in the wrist and fingers flexor muscles (+1 to 3 based on the modified Ashworth scale) Not taking any antispasmodics during the study for at least one month before the study beginning Having minimal grip ability Ability to understand and follow commands Absence of cognitive impairment (Mini-Mental State Examination score >24)

Exclusion criteria:
Recurrent stroke Having other neurological diseases Cervical radiculopathy Fixed contracture in wrist and finger muscles Treatment with other therapies during this study History of physiotherapy treatments in less than a month prior to study History of treatment with dry needling technique after a stroke Previous treatment with nerve blocks or neurolytic agents injection in motor point or Infiltration of botulinum toxin At any time after stroke Uncontrolled hypertension Uncontrolled diabetes Upper limb fracture Any absolute contraindication for using of deep dry needling (such as pregnancy, infection, coagulation defect, seizures or mental disorders, and fear of needles) Reluctance to continue participating in the study

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two equal groups by using of stratified permutation blocks method, with a block size of 4 by using of random allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The treatment will be performed by a physiotherapist and all variables will be measured by another physiotherapist who is unaware of the allocated groups, and the data will be analyzed by a statistician who is unaware of the group assignments.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Shiraz University of Medical Sciences

Street address
School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran

City
Shiraz

Province
Fars

Postal code
7194733669

Approval date
2020-08-19, 1399/05/29

Ethics committee reference number
IR.SUMS.REHAB.REC.1399.028

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Spasticity

Timepoint
Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement
Modified Ashworth scale

2

Description

Muscle thickness of FCU, FCR and FDP; Separately for each muscle, and generally for flexor group.

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Sonography

Secondary outcomes

1

Description

Flexor muscles compressibility

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Sonography

2

Description

Wrist reflex torque

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Isokinetic machine

3

Description

Wrist peak torque

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Isokinetic machine

4

Description

Upper limb motor function

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Fugl-Meyer scale

5

Description

Upper limb skill

Timepoint

Before treatment, after the last treatment session, 1 month after the last treatment sessions

Method of measurement

Box and block test

Intervention groups

1

Description

Intervention group: The intervention consists of 12 sessions (4 weeks, 3 sessions per week) routine physiotherapy treatment for stroke patients, including FES and exercise therapy for at least 40 minutes; And 4 sessions of dry needling treatment on FCU and FCR and FDP muscles once a week.

Category

Rehabilitation

2

Description

Control group: The intervention consists of 12 sessions (4 weeks, 3 sessions per week) routine physiotherapy treatment for stroke patients, including FES and exercise therapy for at least 40 minutes; And 4 sessions of sham dry needling treatment on FCU and FCR and FDP muscles once a week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zahra Rojhani Shirazi

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School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaianzadeh

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Vice Chancellor for Research and Technology, Zand St. Shiraz, Fars The central building of Shiraz University of Medical Sciences, seventh floor,

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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Panahi
Position
PhD candidate in physiotherapy
Latest degree
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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After coordination with the Research Ethics Committee for approval of the ethics committee, participants data file will be provided In complete secrecy and for research purposes only.

When the data will become available and for how long

6 month after acceptance of the article by the journal.

To whom data/document is available

In addition to the principal researcher and the supervisor of the project, upon request, access to information can be reviewed by the Ethics Committee.

Under which criteria data/document could be used

Preferably it is only used for the subject of my research, but if research is to be done in order to use the statistical population, the main project executor and the student's main collaborator will make a decision with the permission of the ethics committee.

From where data/document is obtainable

Executors of the project can first be referred to through Dr. Zahra Rojhani Shirazi (09171127108), and the main colleague and student collaborator Ms Fatemeh Panahi (09183571646).

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

6 months after the article was published, referring the request to the executor of the project, in addition, an official letter from the ethics committee will be commented on in order to obtain a license, and if the ethics committee approves, emphasizing the confidentiality of the information, the requested information will be provided to the applicant.

Comments