

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of histological changes in the biceps brachii muscle after dry needling in stroke patients using the echovariation index: a double-blind Randomized clinical trial

Protocol summary

Study aim

Evaluation Alterations in Biceps Brachii Muscle tissue following dry needling in stroke patients using the echovariation index.

Design

A randomized, double-blind, controlled clinical trial was conducted on 36 patients, accounting for a 10% dropout rate, giving a total of 39 patients. Randomization was performed using the website www.sealedenvelope.com

Settings and conduct

Chronic stroke patients are referred to Dr. Heshmat Hospital's physiotherapy clinic per inclusion criteria and split into three groups after initial assessment. In this double-blind study, patients and assessor are blinded. Group one receives 10 exercise sessions plus 5 alternating dry-needling sessions; group two the same with sham needles; group three only 5 dry-needling sessions. Range of motion, motor function, spasticity severity, and covariance are assessed before, after, and one week post-treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Hemiplegia resulting from a first ischemic stroke Age between 40 and 65 years At least 6 months elapsed since the stroke Spasticity severity of 1 or higher in the elbow flexor muscles No fixed motor limitation in the elbow flexors Exclusion Criteria: History of recurrent stroke Unwillingness to continue participation

Intervention groups

Group 1: Ten sessions of therapeutic exercise and five sessions of dry needling of the biceps (every other session). Group 2: Ten sessions of therapeutic exercise and five sessions of sham needling of the biceps (every other session) at the same points; sham needling uses a plastic monofilament tip resembling a needle. Group 3: Only five sessions of dry needling of the biceps at similar intervals.

Main outcome variables

Brannstrom recovery stage, spasticity severity, elbow range of motion, echo intensity, echovariance index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211030052912N7**

Registration date: **2026-08-03, 1405/05/12**

Registration timing: **prospective**

Last update: **2026-08-03, 1405/05/12**

Update count: **0**

Registration date

2026-08-03, 1405/05/12

Registrant information

Name

Somaye Azarnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7173 2824

Email address

azarnia.pt.82@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-20, 1405/05/29

Expected recruitment end date

2027-08-20, 1406/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of histological changes in the biceps brachii muscle after dry needling in stroke patients using the echovariation index: a double-blind Randomized clinical trial

Public title

Evaluation of histological changes in the biceps brachii muscle after dry needling in stroke patients

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

1 Hemiplegia due to first ischemic stroke Age between 40 and 65 years At least 6 months after stroke Spasticity severity 1 or higher in elbow flexor muscles No use of anti-spasticity drugs during the study period No other nervous system disorders

Exclusion criteria:

Having a second stroke Unwanted to continue cooperation

AgeFrom **40 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **39****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be carried out via the website www.sealedenvelope.com. In this method, 5 blocks of 6 will be determined according to three groups. Then, each sequence will be recorded on a card and placed inside an envelope. In the order of patients' arrival, the envelopes will be opened and the assigned group of that participant will be determined. In this double-blind study, patients and the evaluator will be unaware of the type of group assigned. Randomization and evaluation will be carried out by a person who is not involved in the treatment process of the patients and is unaware of the type of intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, patients and the evaluator are unaware of the type of group assigned. Randomization and evaluation will be performed by a person who is not involved in the treatment process of the patients and is unaware of the type of intervention. For the sham needle, a monofilament head, which is plastic and

resembles a shoe, will be used that is only moved slowly over the skin and does not penetrate into the tissue.

Placebo

Not used

Assignment

Other

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

Keshavarz Blvd., Corner of Qods, Headquarters of Tehran University of Medical Sciences, 6th Floor

City

Tehran

Province

Tehran

Postal code

141765383761

Approval date

2026-07-27, 1405/05/05

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1405.241

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction Incl.: occlusion and stenosis of cerebral and precerebral arteries (including truncus brachiocephalicus), resulting in cerebral infarction

Primary outcomes**1****Description****Timepoint****Method of measurement****2****Description**

Echovariance index

Timepoint

Before starting the intervention, after the treatment ends, and one week after the completion of the sessions.

Method of measurement

Ultrasound and multifrequency linear transducers with a maximum frequency of 11 MHz will be used.

3

Description

Rang of motion

Timepoint

Before starting the intervention, after the treatment ends, and one week after the completion of the sessions.

Method of measurement

By standard goniometer model COMED

4

Description

Functional assessment

Timepoint

Before starting the intervention, after the treatment ends, and one week after the completion of the sessions.

Method of measurement

Upper limb function is evaluated according to the Brunnstrom stages of recovery.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: will receive ten sessions of therapeutic exercise with the Bobath approach and five sessions of dry needling of the biceps muscle (every other session). Method of dry needling of the biceps muscle: the patient is placed in a supine position with the upper limb beside the body and the elbow in extension. Five centimeters above the middle of the elbow crease line (distal one-third of the muscle), the needle is inserted perpendicularly into the motor point of the muscle and moved for 1 minute in a fast in/fast out manner in different directions in a conical pattern.

Category

Rehabilitation

2

Description

Intervention group2:Will receive only five sessions of dry needling of the biceps muscle with intervals similar to the previous groups.

Category

Rehabilitation

3

Description

Control group:Ten sessions of therapeutic exercise with the Bobath approach, along with five sessions of sham needling of the biceps muscle (every other session), will

be administered at the same previous points. For the sham needling, a plastic monofilament tip similar to a needle will be used, which is only slowly moved over the skin and does not penetrate the tissue.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Heshmat hospital

Full name of responsible person

Somaye azarnia

Street address

Dr Heshmat hospital, 15 khordad Ave, Rasht

City

Rasht

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Guilan

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4193955588

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+98 13 3366 9066

Email

heshmat@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

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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**

Rasht University of Medical Sciences

Full name of responsible person

Somaye azarnia

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Dr. Heshmat Hospital, 15 Khordad Blvd., Rasht

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is 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

After de-identifying people, the consent form and evaluation data can be shared.

When the data will become available and for how long

One year after the article was published

To whom data/document is available

Researchers working in educational, research and academic institutions

Under which criteria data/document could be used

For the purpose of conducting research, with obtaining permission, attributing the source, and maintaining data confidentiality.

From where data/document is obtainable

Email, phone number

What processes are involved for a request to access

data/document

One week after sending an email or making a phone call
Comments