# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluation of histological changes in the biceps brachii muscle after dry needling in stroke patients using theechovariation 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**
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**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 theechovariation 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
**Age**
From **40 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target 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**
163
**ICD-10 code description**
Cerebral infarctionIncl.: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
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**Province**
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## 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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**Province**
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141765383761
**Phone**
+98 21 8163 3698
**Email**
vcr@tums.ac.ir
**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**
Assisstant professor
**Latest degree**
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## Person responsible for scientific inquiries

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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**
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**