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 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
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 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
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+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
Keshavarz Blvd., Corner of Qods, Headquarters of Tehran University of Medical Sciences, 6th Floor
City
Tehran
Province
Tehran
Postal code
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
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Dr. Heshmat Hospital, 15 Khordad Blvd., Rasht
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9066
Email
azarnia.pt.82@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Somaye Azarnia
Position
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Dr. Heshmat Hospital,15 Khordad Blvd.,Rasht
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9066
Email
azarnia.pt.82@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Somaye Azarnia
Position
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Dr. Heshmat Hospital,15 Khordad Blvd.,Rasht
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 9066
Email
azarnia.pt.82@gmail.com

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