

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of forearm selective cutaneous anesthesia combined with active sensory re-education on sensory motor function of upper limb in chronic stroke survivors: a prelimi

#### Protocol summary

##### Study aim

to investigate the effect of using active sensory retraining using the Win-Perry and Delon method along with selective afferent denervation of the affected forearm on the sensory-motor function of the upper limb in people with chronic stroke.

##### Design

one group before/after trial

##### Settings and conduct

The therapeutic interventions consisted of 12 60-minute sessions, consisting of 40 minutes of routine occupational therapy and 20 minutes of sensory retraining, every other day. The patients' occupational therapy included the use of infrared radiation for the upper limb for 10 minutes to prepare the tissue, followed by stretching techniques for spastic muscles such as wrist and finger flexors and biceps, followed by active wrist and finger extension exercises and thumb apposition. Sensory retraining exercises are graded and include localization and stereognosis in therapy sessions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with cortical ischemic stroke within the middle cerebral artery in the age of 20-65 years of age. ability to extend the fingers  
Exclusion criteria : having cognitive and visual deficits, neurological surgeries and other neurological diseases, neglect in right hemisphere lesions

##### Intervention groups

Local anesthesia in the forearm with sensory retraining technique

##### Main outcome variables

fugl Meyer Assessment: This assessment is a stroke-specific performance-based index designed to assess motor function, balance, sensation, and joint function in patients with post-stroke hemiplegia. Semmes-Weinstein Monofilament: This discrimination test is used to assess the threshold for stimulation required to perceive light

touch to deep pressure.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250527065928N1**

Registration date: **2025-08-09, 1404/05/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-08-09, 1404/05/18**

Update count: **0**

##### Registration date

2025-08-09, 1404/05/18

##### Registrant information

##### Name

Amin Mahdizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3658 0251

##### Email address

mahdizadeha@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-07-06, 1404/04/15

##### Expected recruitment end date

2025-12-21, 1404/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effects of forearm selective cutaneous anesthesia combined with active sensory re-education on sensory motor function of upper limb in chronic stroke survivors: a prelimi

**Public title**

The effects of forearm selective cutaneous anesthesia combined with active sensory re-education on sensory motor function of upper limb in chronic stroke survivors: a prelimi

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with cortical ischemic stroke limited to the middle cerebral artery based on brain imaging more than 6 months have passed since the stroke patients have an age range of 20 to 65 years a normal level of consciousness based on answering questions and performing actions requested of the patient ability to understand one-step instructions and recognize geometric spatial shapes have a light touch sensation in the fingertips have a level of 4 or higher on the Brannstrom assessment criteria in the hand able to transfer one block of the box and block test have spasticity severity within +1 based on the modified Ashworth criteria

**Exclusion criteria:**

Having cognitive and visual impairments neurological surgeries and other neurological diseases neglect in right hemisphere lesions having impaired sense of touch in the hands and fingers

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **5**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

This study examines the combination of two sensory re-learning interventions along with a temporary local anesthesia method in the forearm for patients with chronic stroke.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of health and paramedical sciences

**Street address**

Occupational Therapy Department, Faculty of Rehabilitation and Paramedical sciences, Kharazmi building, sciences Blvd, Ferdowsi university campus, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Approval date**

2025-04-26, 1404/02/06

**Ethics committee reference number**

IR.MUMS.FHMPM.REC.1404.039

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

CHRONIC STROKE

**ICD-10 code**

I63.01

**ICD-10 code description**

Cerebral infarction due to thrombosis of vertebral artery

**Primary outcomes****1****Description**

fugl meyer upper extremity sensory motor function assessment

**Timepoint**

before intervention and 6,12 weeks after intervention

**Method of measurement**

fugl meyer assessment of sensory-motor function

**Secondary outcomes****1****Description**

Light touch to deep pressure threshold score with monofilament

**Timepoint**

before intervention and 6 ,12 weeks after intervention

**Method of measurement**

semmes-weinstein monofilaments

## Intervention groups

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### Description

Intervention group: Half an hour before the start of sensory interventions, the patient's affected forearm is smeared with lidocaine ointment and a bandage is applied to numb the forearm. Then, graded sensory retraining exercises, including localization and strengosis, are performed in therapy sessions, and at the end of the twelfth session, the results are evaluated and recorded.

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Hashemi Nejad hospital and Ghaem hospital

#### Full name of responsible person

Amin Mahdizadeh

#### Street address

Hashemi Nejad Hospital, end of Vahid Street,  
Mashhad, Ahmad Abad Blvd., Ghaem hospital

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9105788869,9199-9917

#### Phone

+98 51 3840 0001

#### Email

aminmahdizadeh@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi

#### Street address

vice chancellor for research and innovation,  
Ghomeshi building, Daneshgar street, Mashhad

#### City

mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3841 1538

#### Email

vcresearch@mums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Amin Mahdizadeh

#### Position

Assistant professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Occupational Therapy

#### Street address

No 52,shahid purebrahim 2,shahid mohammadi  
10,ghasem abad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

1985713874

#### Phone

+98 51 3658 0251

#### Fax

#### Email

MahdizadehA@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Amin Mahdizadeh

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Assistant professor

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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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

the data will be presented after reasonable request

**When the data will become available and for how long**

After writing article and Data gathering process

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

For metanalysis article

**From where data/document is obtainable**

via contacting with corresponding author

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

via requesting with email as early as possible

**Comments**