

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

1

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 strengenosis, 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

9100788869,9199-9917

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

vise 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

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 updating data

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

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