Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 51 3658 0251

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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
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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 stregenosis, 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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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
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

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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