Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of mobilizing and immobilizing splints on hand motor function in stroke patients

Protocol summary

Summary

Abstract Purpose: We aimed to compare the effect of mobilizing and immobilizing splints on wrist-fingers motor function after stroke. Methods: In this experimental study, we selected 31 stroke patients and divided them randomly into three groups including: mobilizing splint, immobilizing splint and control group. Selected patients have spasticity in their hand based on modified Ashworth scale > 1. Also they have not severe cognitive impairments. Participants in intervention groups wore their own splints for eight weeks, five days per week and on average six hours per day. Motor function was measured by Fugl- Meyer (FM) scale at baseline and eighth week. The one-way ANOVA was used to compare scores of FM scale between three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009294836N1**
Registration date: **2010-11-28, 1389/09/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-28, 1389/09/07

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2009-05-31, 1388/03/10

Expected recruitment end date

2009-10-02, 1388/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of mobilizing and immobilizing splints on hand motor function in stroke patients

Public title

Effect of splints on hand function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hemiplegia in post-stroke patients have occurred more than 12 months before the beginning of the study, having no Botax injection, spasticity score based on modified Ashworth scale>1, no functional movement in involved hand, age between 45 to 75. Exclusion criteria: Presence of non-stroke related problems in involved upper limb, presence of severe cognitive problems.

Age

From **45 years** old to **75 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **31**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Army University of Medical Sciences
Street address
Etemadzadeh Avenue, Fatemi St., Tehran, Iran.
City
Tehran
Postal code
Approval date
2009-05-02, 1388/02/12
Ethics committee reference number
1021

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
motor function
Timepoint
Before the beginning of the study and 8 week after that.
Method of measurement
Fugl-Meyer scale, quantitative

Secondary outcomes

1

Description
spasticity
Timepoint
onset of study, 8th week
Method of measurement
modified Ashworth scale

Intervention groups

1

Description
Participants in mobilizing splint group wore a mobilizing splint for eight weeks, five days per week and on average six hours per day. Mobilizing splint placed on the forearm and hand and allowed patients to move their covered parts by splint just only in Metacarpophalangeal joints. They also received traditional rehabilitation including Bobath exercises.
Category
Rehabilitation

2

Description
Participants in immobilizing splint group wore an immobilizing splint for eight weeks, five days per week and on average six hours per day. Immobilizing splint placed on the forearm and hand and did not permit patients to move any of their covered parts by splint. They also received traditional rehabilitation including Bobath exercises.
Category
Rehabilitation

3

Description
Participants in control group only received traditional rehabilitation including Bobath exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Mohammad Heidari
Street address
Daneshju St., Velenjak, Evin, Tehran, Iran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Army University of Medical Sciences
Full name of responsible person
Mrs. Doctor Fereshteh Dormanesh
Street address
Etemadzadeh Avenue, Fatemi St., Tehran, Iran.
City
Tehran
Grant name
پاین نامه فرهیختگان
Grant code / Reference number
88010
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Army University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Army University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty