

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effects of Adjustable Wrist hand Splint on Spasticity and Active Range of Motion on Post stroke patients

Protocol summary

Summary

Introduction and background: Following stroke, Patients suffer from hand disability. Objectives: This study was conducted to determine effects of adjustable wrist hand Splint on Spasticity and Range of Motion in Post stroke Patients. Design: This study was done by a Clinical trial Setting and conduct: With 15 patients with stroke (aged 40-65) in Occupational clinics of Rofeydeh Rehabilitation Hospital and Faculty of Rehabilitation of Iran University of Medical Sciences. All patients were categorized in two groups of control (8 patients) and experimental (7 patients). Occupational exercises were done for both groups for four weeks and Intervention: Adjustable Wrist hand Splint were used in only experimental group. Eligibility criteria: Men and Women suffered stroke between 6-12 month, and have wrist Spasticity ≥ 1 According to Modified Ashworth scale. Variables: For wrist spasticity and Range of Motion were measured by Modified Ashworth Scale and Goniometry, respectively, before and 4 weeks after of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903193754N2**

Registration date: **2010-06-09, 1389/03/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-09, 1389/03/19

Registrant information

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Iran University of Medical sciences (IUMS)-
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical sciences (IUMS)

Expected recruitment start date

2009-03-13, 1387/12/23

Expected recruitment end date

2009-11-06, 1388/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Adjustable Wrist hand Splint on Spasticity and Active Range of Motion on Post stroke patients

Public title

Effect of Hand Splint on Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age of 40 to 65, 2- Patients within 6-12 month from onset stroke, 3- wrist and finger spasticity more than 1 degree according to modified Ashworth scale 4- no active wrist extension. Exclusion criteria were: 1- History of former stroke 2- Any neurologic disease (such as, Parkinson or Myopathy) Which could intervene the treatment procedure.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Do rehabilitation exercises for both groups. Give splint to experimental group

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rehabilitation School.Iran University of Medical sciences (IUMS)

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Shahnazari Street, Mirdamad blvd.Rehabilitation School

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Tehran

Postal code

439115875

Approval date

2009-02-02, 1387/11/14

Ethics committee reference number

81

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

G81.1

ICD-10 code description

Spastic hemiplegia

Primary outcomes

1

Description

Spasticity

Timepoint

Before study and After 4 weeks

Method of measurement

Modified Ashworth Scale

2

Description

Range of Motion

Timepoint

Before study and After 4 Weeks

Method of measurement

Manual Goniometer

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

In control group,Patients received Rehabilitation therapy for 4 weeks

Category

N/A

2

Description

use the Adjustable Wrist hand Splint for Experimental group for 4 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Occupational Therapy Of Rehabilitation School Iran University of Medical sciences (IUMS)

Full name of responsible person

Malahat Akbarfahimi

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-chancellor for Research, Iran University of Medical University

Full name of responsible person

Maziar Moradi lake

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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

Vice-chancellor for Research, Iran University of Medical University

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**

Iran University of Medical sciences (IUMS)

Full name of responsible person

Mohammad Ali Jvanshir.Eng

Position

Master of Science - Academic member

Other areas of specialty/work**Street address**

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Elahe Tutunchi

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Web page address**Person responsible for updating data****Contact****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*