

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of The effect of Pan Splint and Extention Splint with Tendon Pressure Points on Hand and Wrist Flexors Spasticity and increased range of motion in Patients with Stroke

Protocol summary

Study aim

Comparison of The effect of Pan Splint and Extention Splint with Tendon Pressure Points on Hand and Wrist Flexors Spasticity and increased range of motion in Patients with Stroke

Design

parallel group trial with blinded outcome assessment, Blocked Randomization

Settings and conduct

This study was designed to investigate the effect of two types of splints on spasticity and range of motion in stroke patients. The study is a randomized clinical trial. After referring the patient to the neurology clinic of Hamadan University of Medical Sciences and signing a written consent from the patient or his companion, for each patient information about age, sex, weight, height, time elapsed from the onset of the disease and the affected side of The interview and examination are recorded in the file. We use the blocked method to randomize. The assessments are made by a specialist at the beginning of the visit and are presented to the Technical Orthopedic Center of the Comprehensive Rehabilitation Center of the Rehabilitation Center affiliated to the School of Rehabilitation. And re-evaluated. We will consider this basic information as a control group. The patient will use the relevant splint for 4 weeks and for 8 hours a day, and at the end of 4 weeks he will see the relevant doctor again for re-evaluation. The patient is unaware of the type of splint received.

Participants/Inclusion and exclusion criteria

1. Age between 40-70 2. At least 2 months, up to 5 years disease duration. 3. Wrist and hands flexors MMAS score ≥ 1 4. First-ever stroke 5. No cognition impairment 6.No taking antispastic drugs 7. Excluded diabetic patient 8.Excluded any other neurological disorders

Intervention groups

Pan Splint Group Extention Splint with Tendon Pressure

Points Group

Main outcome variables

Modified Modified Ashworth Scale Passive Range of Motion Active Range of Motion Fugl Mayer functional Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200531047610N1**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

Registration date

2020-06-27, 1399/04/07

Registrant information

Name

Omid Torkaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 2846

Email address

o.torkaman@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-25, 1399/04/05

Expected recruitment end date

2020-10-26, 1399/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The effect of Pan Splint and Extention Splint with Tendon Pressure Points on Hand and Wrist Flexors Spasticity and increased range of motion in Patients with Stroke

Public title

effect of splint on hand spasticity

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

At least two months from last lesion time intensity of wrist and hand spasticity MMAS \geq 1 The first patient to stroke Be able to understand the commands

Exclusion criteria:

Taking an anti spasticity drug There are other neurologic disease Of diabetes contracture more dan ten degrees

AgeFrom **40 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

Not 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**

National Ethics Committee in Biomedical Research

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamadan

City

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Province

Hamadan

Postal code

6517838736

Approval date

2020-06-09, 1399/03/20

Ethics committee reference number

IR.UMSHA.REC.1399.047

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

Sequelae of stroke

ICD-10 code

I69.4

ICD-10 code description

Sequelae of stroke, not specified as haemorrhage or infarction

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

Spasticity

Timepoint

Before After

Method of measurement

Modified Modified Ashworth Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Pan splint

Category

Rehabilitation

2**Description**

Intervention group: Extension Splint with pressure points

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mobasher Rehabilitation Clinic

Full name of responsible person

Omid Torkaman

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Position

lecturer

Latest degree

Master

Other areas of specialty/work

Others

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Omid Torkaman

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Omid Torkaman

Position

lecturer

Latest degree

Master

Other areas of specialty/work

Others

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable