Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The Effect of 6-Week Use of the newly designed anti-spasticity Orthosis on Spasticity, Muscle Function, and Quality of Life in Patients with Stroke and Multiple Sclerosis

Protocol summary

Study aim

To determine the effect of 6 weeks of using a new anti-spasticity orthosis on the level of spasticity, muscle function, and quality of life in patients with stroke and multiple sclerosis

Design

A single-group clinical trial (without control group) designed as a before-and-after comparison of affected side with itself, on 13 patients where blinding is not possible, but the order of measuring outcomes will be randomized.

Settings and conduct

Patients with unilateral spastic hand resulting from multiple sclerosis or stroke who are residents of Qazvin will participate in this study. This research will be conducted to determine the effect of six weeks of using the intervention (a new anti-spastic orthosis) on the parameters of the affected side. For this purpose, an orthosis will be delivered to each individual and the method of use will be taught. Data, which are obtained from the clinical assessment of the involved limb, will be compared before and after using the orthosis. Blinding is impossible for any of the participants or the researcher. The study will take place in Qazvin.

Participants/Inclusion and exclusion criteria

Eligible participants will be adults aged 18 to 65 with a confirmed history of stroke or multiple sclerosis (onset at least 6 months prior), presenting with mild to moderate spasticity per the Modified Ashworth Scale, and demonstrating the ability to comprehend and cooperate. Individuals will be excluded if they have severe upper limb orthopedic conditions, open skin wounds at the proposed orthosis site, or are concurrently using other similar therapeutic devices.

Intervention groups

A self-controlled study examines the 6-week effects of an anti-spastic orthosis on spasticity level in multiple sclerosis/ stroke patients with hemiplegia, without a control group

Main outcome variables

modified Ashworth Scale; muscle strength; quality of life; time of orthosis use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058315N4**
Registration date: **2025-12-02, 1404/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-02, 1404/09/11**
Update count: **0**

Registration date

2025-12-02, 1404/09/11

Registrant information

Name

Nahid Tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-01, 1404/09/10

Expected recruitment end date

2026-10-23, 1405/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of 6-Week Use of the newly designed anti-spasticity Orthosis on Spasticity, Muscle Function, and Quality of Life in Patients with Stroke and Multiple Sclerosis

Public title
Efficacy of a Novel Anti-spasticity Orthosis on Spasticity, Muscle Function, and Quality of Life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The presence of mild to moderate spasticity (according to the Modified Ashworth Scale) A history of stroke or multiple sclerosis at least 6 months prior to the study onset Ability to comprehend and cooperate
Exclusion criteria:
Presence of severe orthopedic conditions in the upper limb open skin wounds at the orthosis site concurrent use of other similar therapeutic devices
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **13**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
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Shahid Fahmideh
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Province
Hamadan
Postal code
6517838840
Approval date
2025-11-05, 1404/08/14
Ethics committee reference number
IR.UMSHA.REC.1404.672

Health conditions studied

1

Description of health condition studied
multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

2

Description of health condition studied
hemiplegia
ICD-10 code
G83.8
ICD-10 code description
Other specified paralytic syndromes

Primary outcomes

1

Description
spasm severity
Timepoint
At baseline and after six-week use of anti-spastic orthosis
Method of measurement
Modified Ashworth scale

2

Description
Quality of life
Timepoint
At baseline and after six-week use of anti-spastic orthosis
Method of measurement
the score of EQ-5D-3L questionnaire

3

Description
Muscle strength
Timepoint
At baseline and after six-week use of anti-spastic orthosis
Method of measurement
manual muscle testing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Each participant will be evaluated under two conditions: at baseline without history of using an antispastic orthosis, and after six-week using the new antispastic orthosis on the affected side, with the evaluation order randomized and a 5-minute rest period between outcome measures. Spasticity evaluation will involve use of the modified Ashworth scale, while the EQ-5D-3L will be used to assess quality of life and the muscle strength will be measured by manual muscle testing, , all conducted at the Bu Ali hospital in Qazvin. There is no control group

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu Ali Sina Hospital

Full name of responsible person
Narges Zeynali

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Sponsors / Funding sources

1

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Grant name
Vice President for Research and Technology, Hamadan University of Medical Sciences

Grant code / Reference number
48304

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

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Assistant professor

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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
No - There is not a plan to make this available
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available