

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effectiveness of hip flexion-assisted orthosis on reducing pain and improving the quality of life in patients with MS

Protocol summary

Study aim

Design, construction and evaluation of the effectiveness of hip flexion orthosis on pain and quality of life in patients with MS

Design

The trial has an intervention group and is performed on 25 people.

Settings and conduct

First, Orthosis Assist Flexion Hip is designed and manufactured based on similar studies and cases. After confirming the design of the orthosis, an evaluation is performed. The participants is referred to the hip flexion (Hip Flexion Assist Orthosis) with the diagnosis of MS according to the expert's opinion. Muscle strength and range of motion of joints, pain and quality of life are assessed before orthosis use. People will be told how to wear, remove, and use orthosis, and they will be asked to use orthosis for a month during walking and daily activities. After a month, the pain and quality of life are evaluated again. During this period, patients are followed up by telephone.

Participants/Inclusion and exclusion criteria

Inclusion criteria: MS in the first stage of recurrence and recovery and expanded disability scale from 4 to 6; with the ability to walk independently, with the highest grade of spasticity 2 based on Ashworth scale; Conditions of absence: history of cardiorespiratory disease; flexion contracture fixed in one of the hip or knee or ankle joints; cognitive disorders

Intervention groups

The orthosis is given to the patient with MS. The use of orthoses is explained to people and they are asked to use orthoses for a month during walking and daily activities. After a month, the pain and quality of life are evaluated again.

Main outcome variables

Design, construction and evaluation of the effectiveness of hip flexion orthosis on pain and quality of life in patients with MS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210522051361N1**

Registration date: **2021-09-23, 1400/07/01**

Registration timing: **prospective**

Last update: **2021-09-23, 1400/07/01**

Update count: **0**

Registration date

2021-09-23, 1400/07/01

Registrant information

Name

Erfan Mobarak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2244 6729

Email address

mobarak.erfan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-09, 1400/09/18

Expected recruitment end date

2022-03-09, 1400/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of hip flexion-assisted orthosis on reducing pain and improving the quality of life in patients with MS

Public title
Evaluation of the effectiveness of hip flexion-assisted orthosis on reducing pain and improving the quality of life in patients with MS

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
MS in the first stage of recurrence and recovery and extended disability scale from 4 to 6; with the ability to Having the ability to walk independently with the maximum grade of spasticity 2, based on Ashworth scale
Exclusion criteria:
Positive history of cardiorespiratory disease Fixed Flexion contracture of hip knee or ankle joint Cognitive disorders

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

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

Vice Chancellor for Research, Iran University of Medical Sciences

Street address

Iran university of medical science

City

Tehran

Province

Tehran

Postal code

Approval date

2021-07-27, 1400/05/05

Ethics committee reference number

IR.IUMS.REC1400.404

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Check for pain

Timepoint

30 day

Method of measurement

Pain Visual Analogue Scales

2

Description

Quality of life specific to MS patients

Timepoint

30 Day

Method of measurement

multiple sclerosis quality of life questionnaire

3

Description

General quality of life

Timepoint

30 day

Method of measurement

short form 36 health survey questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants are referred to the hip flexion assist orthosis with the diagnosis of MS according to the expert's opinion. Muscle strength and range of motion of joints, pain and quality of life are assessed before orthosis use. People are explained how to wear, remove and use orthoses and are asked to use orthoses for a month during walking and daily activities. After a month, the pain and quality of life are assessed again. During this time, patients are followed up by telephone.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Bijan Forough

Street address

Firoozgar Hospital, Beh Afarin Ave

City

Tehran

Province

Tehran

Postal code

15937 48711

Phone

+98 21 2244 6729

Email

mobarak.erfan@gmail.com

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mohaddese Azadvari

Street address

Sina Hospital, Amir Kabir Ave

City

Tehran

Province

Tehran

Postal code

11367 46911

Phone

+98 21 2244 6729

Email

mobarak.erfan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Bijan Forough

Street address

Beh Afarin Ave, Firoozgar Hospital

City

Tehran

Province

Tehran

Postal code

15937 48711

Phone

Email

mobarak.erfan@gmail.com

Grant name

Neuromusculoskeletal Research Center

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Erfan Mobarak

Position

Colleague

Latest degree

Master

Other areas of specialty/work

Robotic

Street address

No 15, 10th kangan Ave, Vezarat Omour Khareje Ave, Artesh Blvd

City

Tehran

Province

Tehran

Postal code

1955654711

Phone

+98 21 2244 6729

Fax

Email

mobarak.erfan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Bijan Forough

Position

Professor

Latest degree

Specialist
Other areas of specialty/work
Physical Medicine
Street address
Firoozgar Hospital, Beh Afarin Ave.
City
Tehran
Province
Tehran
Postal code
15937 48711
Phone
+98 21 2244 6729
Fax
Email
mobarak.erfan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Masumeh Bagherzadeh Cham
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
orthosis and prosthesis
Street address
Firoozgar Hospital, beh Afarin Ave.
City

Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1612
Fax
Email
BagherzadehCham.m@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available