

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Evaluation of the effect of lower limb multifunctional orthosis in patients with foot drop

Protocol summary

Study aim

Determining the effect of multifunctional lower limb orthosis in patients with foot drop

Design

The clinical trial is accessible to 20 patients with foot drop.

Settings and conduct

Patients who refer to the clinics of physical medicine and rehabilitation specialists affiliated to Shiraz University of Medical Sciences as well as the physiotherapy clinic of the Faculty of Rehabilitation are selected. 20 of these patients were admitted to the study with easy access and before, immediately and 3 months after using multifunctional lower limb orthosis, the patients were analyzed by Kistler force plate and Qualysis motion analysis system software. Patients are also asked to complete the SF-12 quality of life questionnaire and the lower extremity functional scale questionnaire before and 3 months after orthosis use. The data will then be collected and analyzed by SPSS software version 16.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients who were able to walk independently, needed a mobility aid, and foot drop due to a lower motor neuron disorder caused by trauma, injection, discopathy, etc. and Have not used orthoses to correct foot drop.

Intervention groups

20 patients with foot drop wear multi-purpose lower limb orthoses made in the Rehabilitation Faculty of Shiraz University of Medical Sciences.

Main outcome variables

The degree of foot drop The rate of kinetic and kinematic changes in gait analysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210715051897N1**

Registration date: **2021-08-04, 1400/05/13**

Registration timing: **prospective**

Last update: **2021-08-04, 1400/05/13**

Update count: **0**

Registration date

2021-08-04, 1400/05/13

Registrant information

Name

Mohammad Amin Vafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3722 1366

Email address

mohammad313amin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of lower limb multifunctional orthosis in patients with foot drop

Public title

Evaluation of the effect of lower limb multifunctional

orthosis in patients with foot drop

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

have foot drop Be independent in walking Need a mobility aid Foot drop due to damage to the lower motor neurons caused by trauma, injection, discopathy, etc They have never used orthosis to correct foot drop Do not have progressive neurological disease There are no restrictions on the movement of the lower limb joints Have no history of stroke, lower limb orthopedic surgery, rheumatic diseases, or orthopedic problems affecting gait and balance. Can walk 10 meters without a mobility aid Not more than 2 years have passed since the foot drop The recovery process is not fast

Exclusion criteria:

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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 Shiraz University of Medical Sciences

Street address

Secretariat of the Ethics Committee of University Research, Vice Chancellor for Research and Technology, 7th Floor, Shiraz University of Medical Sciences, Zand St., Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶۱۳۵۶۵

Approval date

2021-01-18, 1399/10/29

Ethics committee reference number

61.IR .SUMS.MED.REC.1400

Health conditions studied

1

Description of health condition studied

foot drop

ICD-10 code

M21.37

ICD-10 code description

Foot drop (acquired)

Primary outcomes

1

Description

The degree of foot drop

Timepoint

Before and immediately and 3 months after wearing orthoses

Method of measurement

Goniometer

2

Description

The measure of kinetic and kinematic changes in walking

Timepoint

Before and immediately and 3 months after wearing orthoses

Method of measurement

Kistler force plate system and Qualysis motion analysis system software

Secondary outcomes

1

Description

Performance of Patients with foot drop

Timepoint

Before and 3 months after wearing orthoses

Method of measurement

Lower extremity functional scale questionnaire

2

Description

Quality of life score of patients with foot drop in the Short Form Health Survey questionnaire

Timepoint

Before and 3 months after wearing orthoses

Method of measurement

12-item Short Form Health Survey

Intervention groups

1

Description

Intervention group: 20 patients with foot drop wear multi-purpose lower limb orthoses made in the Rehabilitation Faculty of Shiraz University of Medical Sciences.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation

Full name of responsible person

mohammad amin vafaei

Street address

Faculty of Rehabilitation Sciences, Abivardi St. 1,
Chamran Blvd., Shiraz

City

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Phone

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Email

Rehab@Sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeianzadeh

Street address

seventh floor, the central building of Shiraz University
of Medical Sciences, next to the Red Crescent, Zand
St., Shiraz

City

Shiraz

Province

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۷۱۳۴۸۱۴۳۳۶

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

mohammad amin vafaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Alavi Dormitory, Alley 2, Mulla Sadra St., Namazi
Square

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Shiraz

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Phone

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Email

webadmin@shirazu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

mohammad amin vafaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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

Shiraz University of Medical Sciences

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Phone

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts from 2021

To whom data/document is available

Anyone interested can access this data

Under which criteria data/document could be used

We do not set any specific conditions for the use of the data.

From where data/document is obtainable

mohammad313amin@yahoo.com

What processes are involved for a request to access data/document

After sending the email, applicants can access the documents and data files within a period of 1 month.

Comments