

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of a Newly Designed Orthosis with the Capability of Neuromuscular Electrical Stimulation on the Morphology and Strength of Abductor Hallucis Muscle and Correction of Deformity in Women with Mild to Moderate Hallux Valgus Deformity

Protocol summary

Study aim

Evaluation of the effect of designed orthosis with the capability of neuromuscular electrical stimulation on the morphology and strength of the abductor hallucis muscle and correction of deformity in women with mild to moderate hallux valgus deformity

Design

Randomized clinical Trial with intervention and control groups, Parallel group design, non randomized on 40 participants with mild or moderate hallux valgus deformity and followed for one month

Settings and conduct

Participants will be selected from women referring to the foot clinic or orthotics and prosthetics clinic of the Faculty of Rehabilitation Sciences, Iran University of Medical Sciences. Test conditions and the amount of participation required for individuals will be explained. The volunteers, will sign the consent form. Demographic information will be completed; the necessary assessments will then be made.

Participants/Inclusion and exclusion criteria

Criteria for non-entry: Have any Metal Parts on the Foot for MRI Examination History of Orthosis Treatment for Hallux Valgus Deformity Rigid Flat Foot and Foot Posture Index above 9 Inclusion Criteria: Bilateral or One Sided Hallux Valgus Deformity at Mild or Moderate Severity 1-10 Score Based on Beck Depression Questionnaire Age Between 19-44 Years History of Pain only in the First Metatarsophalangeal Joint for at least One Month Conscious Consent of Participants Accept Study Conditions (for example: Not Wearing Inappropriate Shoes)

Intervention groups

One group will apply electrical stimulation and orthosis for 3 weeks and begin exercise and end at the end of the fourth week. The second group will receive the orthosis

for four weeks, and then the process of starting a treatment program will be similar to the previous group.

Main outcome variables

Angle: intermetatarsal angle: volume, cross sectional area and strength of abductor hallucis muscle: Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048725N1**

Registration date: **2020-12-03, 1399/09/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-03, 1399/09/13**

Update count: **0**

Registration date

2020-12-03, 1399/09/13

Registrant information

Name

Maryam Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

jalali.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a Newly Designed Orthosis with the Capability of Neuromuscular Electrical Stimulation on the Morphology and Strength of Abductor Hallucis Muscle and Correction of Deformity in Women with Mild to Moderate Hallux Valgus Deformity

Public title

The Effect of a Newly Designed Orthosis on the Hallux Valgus Deformity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Bilateral or One Sided Hallux Valgus Deformity at Mild or Moderate Severity 1-10 Score Based on Beck Depression Questionnaire Age Between 19-44 Years No Rigid Flat Foot and Foot Posture Index (FPI) above 9 History of Pain only in the First Metatarsophalangeal Joint for at least One Month Conscious Consent of Participants Accept Study Conditions (for example: Not Wearing Inappropriate Shoes) Do not Have any Metal Parts on the Foot (Such as Artificial Joints or Any Type of Metal Plate and Bolts) for Magnetic Resonance Imaging (MRI) No History of Orthosis Treatment for Hallux Valgus Deformity

Exclusion criteria:

History of Foot Surgery Body Mass Index of 30 or more or Very High Weight (100 kg and above) History of Systemic Diseases Like Rheumatoid Arthritis, Diabetes, Gout, Leprosy; Neurological Disorders and Dislocation and Fracture of Metatarsophalangeal Joints Experience pain Somewhere other than the First Metatarsophalangeal Joint. For Example, People with Symptomatic Flat Feet and Heel Pain

AgeFrom **19 years** old to **44 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **40****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**

Ethics committee of Iran University of Medical Sciences

Street address

Golestan Hemmat Dormitory, Faculty of Rehabilitation Sciences, Madadkaran St., Shah Nazari St., Madar Square, Mirdamad Blvd., Tehran. Postal code: 1545913487

City

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Approval date

2020-07-21, 1399/04/31

Ethics committee reference number

IR.IUMS.FMD.REC.1399.363

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

Hallux Valgus Deformity

ICD-10 code

M20.10

ICD-10 code description

Hallux valgus (acquired), unspecified foot

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

Hallux Valgus Angle

Timepoint

Before and After of the Intervention

Method of measurement

Goniometer and MRI

Secondary outcomes**1****Description**

Abductor Hallucis Muscle Strength

Timepoint

Before and After the Intervention

Method of measurement

Loadcell

2

Description

Volume of Abductor Hallucis Muscle

Timepoint

Before and After the Intervention

Method of measurement

MRI

3

Description

Cross Sectional Area of Abductor Hallucis Muscle

Timepoint

Before and After the Intervention

Method of measurement

MRI

4

Description

Intermetatarsal Angle

Timepoint

Before and After the Intervention

Method of measurement

MRI

5

Description

Range of Motion of First Metatarsophalangeal Joint

Timepoint

Before and After the Intervention

Method of measurement

Goniometer

6

Description

Disability

Timepoint

Before and After the Intervention

Method of measurement

FAAM Questionnaire

Intervention groups

1

Description

Intervention group: This group will use the newly designed orthosis with the capability of neuromuscular electrical stimulation for four weeks. Electrical stimulation will be performed based on the schedule for 3 weeks and three times a week. From the middle of the third week, with the gradual exclusion of electrical stimulation, therapeutic exercise will be performed until the end of the fourth week. This is a toe spread out exercise that has three phases and greatly contracts the

abductor hallucis muscle. This exercise will be done twice a day for 15 minutes. Clinical evaluations and MRI will be performed before and after treatment. Then the combination of orthosis and exercise therapy will continue for only three months and clinical evaluations will be repeated at the end of 3 months.

Category

Rehabilitation

2

Description

Control group: This group will use the newly designed orthosis for four weeks without the capability of neuromuscular electrical stimulation. Therapeutic training will begin in the middle of the third week and will continue until the end of the fourth week. In this group also clinical evaluations and MRI will be performed before and after treatment. Then the combination of orthosis and exercise therapy will continue for only three months and clinical evaluations will be repeated at the end of 3 months.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences, Faculty of Rehabilitation, Orthotic and Prosthetic Department

Full name of responsible person

Dr Maryam Jalali

Street address

Faculty of Rehabilitation Sciences, Madadkaran St., Shah Nazari St., Madar Square, Mirdamad Blvd., Tehran. Postal code: 1545913487

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nasrin.mouloudi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology, Iran University of Medical Sciences

Street address

School of Rehabilitation Sciences, Madadkaran St.,

Shah Nazari St., Madar Square, Mirdamad Blvd.,
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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

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

Maryam Jalali

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Position

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Latest degree

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Other areas of specialty/work

Others

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Person responsible for updating data

Contact

Name of organization / entity

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Position

PhD Candidate of Orthotics and Prosthetics

Latest degree

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Other areas of specialty/work

Others

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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 more information.

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable