

# 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

**Age**

From **19 years** old to **44 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target 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**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**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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**Email**

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.,  
Tehran. Postal code: 1545913487

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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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**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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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**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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