Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of medial arch support with metatarsal pad with and without exercise on the degree of deviation, satisfaction and pressure distribution in people with mild to moderate hallux valgus

Protocol summary

Study aim

this study aimed to compare the hallux valgus angle, range of motion of the first metatarsophalangeal joint, maximum pressure, level of satisfaction in people with hallux valgus in three intervention groups (Arch support, Arch support with metatarsal pad, Arch support with metatarsal pad with exercise) during the periods before treatment, and one month after treatment.

Design

The clinical trial has three 15-parallel intervention groups (medial arch support , medial arch support with metatarsal pad, medial arch support with metatarsal pad and exercise) in a single-blind manner. Randomization for allocation to groups was done with online random number generation software.

Settings and conduct

The study will be conducted in Iran University of Medical Sciences and goniometer, questionnaire and foot scan will be used for evaluation in this study. The participants were unaware of the type of foot orthosis received.

Participants/Inclusion and exclusion criteria

Women 18 to 60 years with mild to moderate hallux valgus deformity according to Manchester index / normal body mass index / no history of foot surgery, no deformity other than hallux valgus in foot, no vascular disease, diabetes and rheumatoid arthritis

Intervention groups

Three intervention groups (medial arch support , medial arch support with metatarsal pad, medial arch support with metatarsal pad and exercise)

Main outcome variables

Hallux valgus angle/ range of motion of the 1st metatarsophalangeal joint /maximum pressure /satisfaction level

General information

Reason for update

This update is done to report the changes in the process of conducting this trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220413054531N1**
Registration date: **2022-05-08, 1401/02/18**
Registration timing: **prospective**

Last update: **2024-11-02, 1403/08/12**
Update count: **1**

Registration date

2022-05-08, 1401/02/18

Registrant information

Name

Kimia Moradiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6698 9321

Email address

kimia.moradiani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

2022-07-25, 1401/05/03

Actual recruitment end date

2023-03-11, 1401/12/20

Trial completion date
2023-03-11, 1401/12/20

Scientific title
The effect of medial arch support with metatarsal pad with and without exercise on the degree of deviation, satisfaction and pressure distribution in people with mild to moderate hallux valgus

Public title
The effect of medial arch support with metatarsal pad with and without exercise on Hallux valgus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Mild to moderate HV (level B and C Manchester criteria) in both feet normal body mass index

Exclusion criteria:
history of surgery in foot history of vascular diseases, diabetes and rheumatoid arthritis other deformities except HV in foot

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization tool: online random number generation software Using the numbers that are randomly generated in the software, each participant receives a specific number and randomly in three groups: insole with arch support, arch support with metatarsal pad and arch support with metatarsal pad with exercise

Blinding (investigator's opinion)
Single blinded

Blinding description
All participants will be given insoles and exercise, but the type of insole and exercise will not be recognizable to individuals

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
Iran University of Medical Sciences, Hemmat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2022-04-27, 1401/02/07

Ethics committee reference number
IR.IUMS.REC.1401.066

Health conditions studied

1

Description of health condition studied
Hallux Valgus

ICD-10 code
M20.1

ICD-10 code description
Hallux valgus (acquired)

Primary outcomes

1

Description
Hallux valgus angle

Timepoint
Before the intervention and one month after the intervention

Method of measurement
Goniometer

2

Description
The range of motion of the first metatarsophalangeal joint

Timepoint
Before the intervention and one month after the intervention

Method of measurement
Goniometer

3

Description
Satisfaction level

Timepoint
Before the intervention and one month after the intervention

Method of measurement
Foot and Ankle Outcome Score (FAOS)

4

Description
maximum pressure
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Foot scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Arch support made of PVC will be adapted for each person and the participants will be asked to use the insole 5 days a week and 6 hours a day.
Category
Treatment - Devices

2

Description
Intervention group: Arch support with metatarsal pad made of PVC will be adapted for each person and the participants will be asked to use the insole 5 days a week and 6 hours a day
Category
Treatment - Devices

3

Description
Intervention group: Arch support with metatarsal pad made of PVC will be adapted for each person and the participants will be asked to use the insole 5 days a week and 6 hours a day In this group, in addition to insoles, special hallux valgus exercises and abductor and flexor muscles of the big toe will be taught to people and people will be asked to do exercises twice a day and ten times each time.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of rehabilitation sciences Iran university of Medical sciences
Full name of responsible person
Hasan saeedi
Street address
Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Madadkaran St., Mad Nazar St., Mirdamad, Mirdamad, Tehran
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Tehran
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Tehran
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1545913487
Phone
+98 21 2222 7124
Email
saeedi.h@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Kiwani
Street address
Fifth floor of the headquarters, Iran University of Medical Sciences, , Hemmat Highway next to Milad Tower
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1449614535
Phone
+98 21 8670 2504
Email
adminsite@iums.ac.ir
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
Hasan Saeedi
Position
Associate Professor

Latest degree
Ph.D.
Other areas of specialty/work
Orthotics And prosthetics
Street address
Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Maddakaran St., Shah Nazari St., Mirdamad, Madar Square
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
Plantar pressure data, Hallux valgus angle data, satisfaction level data before and after interventions It can be shared after identifying people.
When the data will become available and for how long
12 months after the results were published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Scientific research and treatment of patients The use of data is possible only by mentioning the name and organizational affiliation of the executor and colleagues of the published project and article
From where data/document is obtainable
Contact Dr. Hassan Saeedi by email Email: saeedi.h@iums.ac.ir
What processes are involved for a request to access data/document
If the data is used in scientific and therapeutic activities, the information will be provided to the people as soon as possible
Comments