

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Assessment the effect of toe separator orthosis on plantar pressure in subjects with Hallux Valgus

Protocol summary

Summary

(1) Objectives: The toe separator orthosis is one of the known methods to prevent the progression of hallux valgus by correcting the big toe alignment and changing plantar pressure. The aim of this study is to assess the effect of toe separator on plantar pressure redistribution in subjects with Hallux Valgus. (2) Design: quasi-experimental study, single group pre/post test (3) Setting and conduct: The participants will be chosen among the female students and staff of University of Social Welfare and Rehabilitation Sciences. Plantar pressure will be measured by Pedar-X insole system. Tests were consisted of two walking trials: wearing standard shoe only and shoe with toe separator. (4) Participants: 20 females with Hallux Valgus will be recruited on base of single nonprobability sampling. All participants will meet the inclusion criteria included having mild to moderate flexible HV. Participants will be excluded from the study if they had experienced traumatic injuries or surgeries in the lower limbs, leg length discrepancy, pathologic condition or neurologic disorder in feet and deformities other than HV in the forefoot (5) Intervention: The silicon toe separator orthosis Apply to the treatment of hallux valgus. It prevents thumb valgus and control hallux valgus. Participants will be asking to insert this pad between the thumb and second toe and immediate effect of orthosis on plantar pressure will be measured. (6) Main outcome: The variables including peak pressure, force and contact area will be calculated for five regions in forefoot.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090314554N1**

Registration date: **2013-10-19, 1392/07/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-19, 1392/07/27

Registrant information

Name

Zahra Safaeepour

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0083

Email address

z.safaeepour@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of toe separator orthosis on plantar pressure in subjects with Hallux Valgus

Public title

Effect of toe separator in Hallux valgus subjects

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: having mild to moderate flexible HV; age between 19-44. Exclusion criteria: experienced traumatic injuries or surgeries in the lower limbs; leg length discrepancy; pathologic condition or neurologic disorder in feet; deformities other than HV in the forefoot.

Age

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

Gender

Female

Phase

2-3

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 University of Social Welfare and Rehabilitation Sciences

Street address

Ebne sina building, Koodakyar Alley, Daneshjoo Blvd, Evin

City

Tehran

Postal code

Approval date

2012-02-11, 1390/11/22

Ethics committee reference number

24192/2/801/90/Ī

Health conditions studied

1

Description of health condition studied

Hallux valgus

ICD-10 code

M20.1

ICD-10 code description

Acquired deformities of fingers and toes

Primary outcomes

1

Description

Contact area

Timepoint

Before and after intervention

Method of measurement

Plantar pressure measurement system (pedar)

2

Description

Force

Timepoint

Before and after intervention

Method of measurement

Plantar pressure measurement system (pedar)

3

Description

Peak pressure

Timepoint

Before and after intervention

Method of measurement

Plantar pressure measurement system (pedar)

Secondary outcomes

empty

Intervention groups

1

Description

The silicon toe separator orthosis Apply to the treatment of hallux valgus. It prevents thumb valgus and control hallux valgus deterioration. Participants will be asking to insert this pad between the thumb and second toe and immediate effect of orthosis on plantar pressure will be taken by pedar system.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Maede Farzadi

Street address

Koodakyar Alley, Daneshjoo Blvd, Evin

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Maryam Falsafian

Street address

Koodakyar Alley, Daneshjoo Blvd, Evin

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, University of Social Welfare and Rehabilitation Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Zahra Safaeepour

Position

PHD of Biomedical Engineering- Biomechanics

Other areas of specialty/work

Street address

Department of Prosthetics and Orthotics, Koodakyar Alley, Daneshjoo Blvd, Evin

City

Tehran

Postal code

Phone

+98 21 2218 0049

Fax

Email

z.safaeepour@uswr.ac.ir

Web page address

www.uswr.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Maede Farzadi

Position

MS student of Technical Orthopedics

Other areas of specialty/work

Street address

Koodakyar Alley, Daneshjoo Blvd, Evin

City

Tehran

Postal code

Phone

+98 21 7713 2371

Fax

Email

farzadimaede@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Maede Farzadi

Position

MS student of Technical Orthopedics

Other areas of specialty/work

Street address

Koodakyar Alley, Daneshjoo Blvd, Evin

City

Tehran

Postal code

Phone

+98 21 7713 2371

Fax

Email

farzadimaede@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty