

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

To Compare the effects of static and dynamic orthoses on Pain, hallux valgus angle and range of motion in hallux valgus sufferers.

Protocol summary

Summary

The aim of this study is to compare the effects of dynamic and static orthoses on hallux valgus angle, range of motion and pain. The study design is crossover and the participants are both male and female and 19 to 33 years old that are volunteers from the students of Iran University of Medical Sciences that will choose based on single non-probability sampling. A total of 24 subjects will examine. Participant assign to one of the two groups: dynamic orthosis or night splint. The inclusion criteria including of: mild and moderate hallux valgus (based on Manchester scale), minimum pain level of 2 (based on VAS) and 10% limitation in first metatarsophalangeal joint range of motion (measure by Goniometer). The patients with the history of hallux valgus surgery, any history of orthoses use, diseases such as rheumatoid arthritis, diabetes, gout, leprosy, and neurologic disorders will exclude from the study. All subjects will wear each orthosis for a month and after a one-week wash out period, the second orthosis will be replaced.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605215520N8**

Registration date: **2016-07-02, 1395/04/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Mojtaba Kamyab

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

kamyab@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2016-08-12, 1395/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To Compare the effects of static and dynamic orthoses on Pain, hallux valgus angle and range of motion in hallux valgus sufferers.

Public title

A comparison between the effects of two types of orthosis in hallux valgus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Mild to moderate hallux valgus (based on Manchester scale); minimum pain level of 2 (based on Visual Analogue Scale); 10% limitation in first metatarsophalangeal joint range of motion (measure by Goniometer); 19 to 33 years old Exclusion criteria: history of hallux valgus surgery; using orthoses; other

affecting diseases such as rheumatoid arthritis, diabetes, gout, leprosy, and neurologic disorders

Age

From **19 years** old to **33 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

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

School of Rehabilitation Sciences, Nezam St, ShahNazari St, Mother Sq.

City

Tehran

Postal code

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

IR.IUMS.rec.1395.27832

Health conditions studied

1

Description of health condition studied

Hallux Valgus

ICD-10 code

Q66.9

ICD-10 code description

Congenital deformity of feet, unspecified

Primary outcomes

1

Description

Hallux Valgus Angle

Timepoint

Before and after one month follow up

Method of measurement

Goniometer

2

Description

Passive range of motion of first MTP

Timepoint

Before and after one month follow up

Method of measurement

Goniometer

3

Description

Pain

Timepoint

Before and after one month follow up

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

In this study, two types of static and dynamic orthosis used separately. Every person counts as its own control and is compared with itself. Even a month use of dynamic orthoses after the wash-out period, night splint will use.

Category

Treatment - Other

2

Description

Because the study is cross-over, the conditions for this group are same as the previous group. Even a month use of night splint after the wash-out period, dynamic orthoses will use.

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

Mojtaba Kamyab

Street address

Department of Orthotics and prosthetics, School of
Rehabilitaion Sciences, Nezam St, ShahNazari St,
Mother Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Iran University of
Medical Sciences

Full name of responsible person

Mojtaba Kamyab

Street address

Department of Orthotics and prosthetics, School of
Rehabilitaion Sciences, Nezam St, ShahNazari St,
Mother Sq.

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, Iran University of Medical
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

Iran University of Medical Sciences

Full name of responsible person

Mojtaba Kamyab

Position

PhD Orthotics & Prosthetics

Other areas of specialty/work

Street address

Department of Orthotics and prosthetics, School of
Rehabilitaion Sciences, Nezam St, ShahNazari St,
Mother Sq.

City

Tehran

Postal code

Phone

+98 21 2225 8769

Fax

Email

Mojtaba.kamyab@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mojtaba Kamyab

Position

PhD Orthotics & Prosthetics

Other areas of specialty/work

Street address

Department of Orthotics and prosthetics, School of
Rehabilitaion Sciences, Nezam St, ShahNazari St,
Mother Sq.

City

Tehran

Postal code

Phone

+98 21 2225 8769

Fax

Email

Mojtaba.kamyab@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nasrin Mouloudi

Position

Master Student in Orthotics & Prosthetics

Other areas of specialty/work

Street address

Golestan Drom, Nezam St, ShahNazari St, Mother Sq.

City

Tehran

Postal code

Phone

+98 21 2225 6434

Fax

Email

Nasrin.mouloudi@gmail.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