

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effects of foot insole with skive technique and insole with medial wedge on postural control parameters in flexible flat foot population

Protocol summary

Study aim

The aim of this study is to compare the effects of foot insole with skive technique and insole with medial wedge on postural control parameters in flexible flat foot population

Design

This clinical trial will conduct on only one group include 20 flat foot patients for determining the effects of foot insole with skive technique and insole with medial wedge on postural control parameters in flexible flat foot population

Settings and conduct

This study will be conducted in Hamadan university of medical science. Insoles will be fabricated according to skive method. After that, postural control (center of pressure) parameters will be measured with kistler force plate and analyses with qualysis soft ware.

Participants/Inclusion and exclusion criteria

People with having informed consent about participating in research, +6 foot posture index or more, having flexible according to the tiptoe test data will be included in this study. People with having rigid flat feet, having history of neurological disorders, such as Cerebral Palsy (CP), Polio and spina bifida or having lower limb length discrepancy history of surgery in the lower limb will exclude in this study.

Intervention groups

Insole fabricated with the skive technique and insole with medial wedge, In one session of 60 minute.

Main outcome variables

center of pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190919044818N4**

Registration date: **2023-08-14, 1402/05/23**

Registration timing: **prospective**

Last update: **2023-08-14, 1402/05/23**

Update count: **0**

Registration date

2023-08-14, 1402/05/23

Registrant information

Name

Ensieh Pourhosaingholi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4480 3255

Email address

ensiehpmd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of foot insole with skive technique and insole with medial wedge on postural control parameters in flexible flat foot population

Public title

Efficacy of insole on flexible flat foot

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent about participating in research having flexible flat foot according to the tiptoe test data +6 grade foot posture index or more

Exclusion criteria:

having rigid flat feet having history of neurological disorders, such as Cerebral Palsy (CP), Polio and spina bifida having lower limb length discrepancy history of surgery in the lower limb

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

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**

Ethical commete of Hamadan univesity of medical science

Street address

Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Hamadan University of Medical Sciences Shahid Fahmideh Aven..., Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2023-07-05, 1402/04/14

Ethics committee reference number

IR.UMSHA.REC.1402.282

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

Flexible flat foot

ICD-10 code

M21.40

ICD-10 code description

Flat foot [pes planus] (acquired), unspecified foot

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

center of pressure

Timepoint

Before intervention and immidiatly after intervention

Method of measurement

using force plate

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: using insole with skive technique and insole with medial arch in one session 60 minute with camera and force plate

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hamadan university of medical science

Full name of responsible person

Ensieh Pourhoseingholi

Street address

Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Hamadan University of Medical Sciences Shahid Fahmideh Aven..., Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 918 339 9369

Email
ensiehpmd@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza Shokohi

Street address
Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences Shahid Fahmideh Aven., Hamadan,
Iran

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 918 339 9369

Email
ensiehpmd@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Ensieh Pourhoseingholi

Position
Assistant professore

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of

Medical Sciences Shahid Fahmideh Aven., Hamadan,
Iran

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 918 339 9369

Email
ensiehpmd@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Ensieh Pourhoseingholi

Position
Assistant professore

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences Shahid Fahmideh Aven., Hamadan,
Iran

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 918 339 9369

Email
ensiehpmd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Ensieh pourhoseingholi

Position
Assistant professore

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences Shahid Fahmideh Aven., Hamadan,
Iran

City

Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 918 339 9369
Email
ensiehpmd@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Efficacy of insole on flat foot walking

When the data will become available and for how long

After publication of article in 1403

To whom data/document is available

researchers

Under which criteria data/document could be used

For research in health care system

From where data/document is obtainable

By e-mail to ensieh Pourhoseingholi
ensiehpmd@yahoo.com

What processes are involved for a request to access data/document

By e-mail to ensieh Pourhoseingholi

Comments