

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Immediate effect of medical shoe on the gait kinetics in children with Flexible Flatfoot

Protocol summary

Study aim

The Immediate effect of medical shoe on the gait kinetics in children with Flexible Flatfoot

Design

24 Patients will be included in the study non-randomly

Settings and conduct

This study will be conducted on children with flexible flat feet. The subjects in this study will be selected from the patients referred to the Orthosis and Prosthetics department, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences. Before the main test, first, the steps and objectives of the test are explained to the eligible people (parents of the child), then each of the parents of the children participating in the study completes the consent form. The information needed for people to enter the study will be collected through face-to-face questions, FPI questionnaires and clinical test. levels: • Randomly, using a lottery, we determine the order of testing three shoe modes. • 5 minutes of walking before the test for more adaptation • Using the force plate Kistler model, we ask the child to walk on the force plate once with normal shoes, once with thick-soled medical shoes and another time with thin-soled medical shoes at the same speed. • COP and parameters of vertical forces of ground reaction, anterior posterior and internal external forces of ground reaction during walking are measured and examined in three test conditions.

Participants/Inclusion and exclusion criteria

inclusion criteria sever and moderate flexible flatfoot based on FPI-6 Bilateral flexible flatfoot age 6-10 without fracture and surgery without systemic disease like CP or Rickets without Genuvalgum and Genuvarum exclusion criteria: dissatisfaction for continuing uncomfortable to continue the test

Intervention groups

the effect of three types of medical shoes with hard soles, medical shoes with soft soles and normal shoes on the ground reaction force

Main outcome variables

Ground reaction force Center of pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140219016643N10**

Registration date: **2023-11-26, 1402/09/05**

Registration timing: **retrospective**

Last update: **2023-11-26, 1402/09/05**

Update count: **0**

Registration date

2023-11-26, 1402/09/05

Registrant information

Name

Behshid Farahmand

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

farahmand.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Immediate effect of medical shoe on the gait kinetics in children with Flexible Flatfoot

Public title
The Immediate effect of medical shoe on the gait kinetics in children with Flexible Flatfoot

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 moderate and sever flexible flatfoot based onFPI-6
 Bilateral flexible flat foot age 6-10 non fracture and surgery without systemic disease like CP or rickets without genuvalgum or genuvarum
Exclusion criteria:
 The person's lack of consent to continue cooperation The feeling of discomfort or fatigue of the person in such a way that she is not able to continue cooperation.

Age
From **6 years** old to **10 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
N/A

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

Shahrake Quds - between South Flamak and Zarafshan - Simai Iran - Ministry of Health headquarters

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2022-08-10, 1401/05/19

Ethics committee reference number

IR.IUMS.REC.1401.414

Health conditions studied

1

Description of health condition studied

flexible flat foot

ICD-10 code

Q66.5

ICD-10 code description

Congenital pes planus

Primary outcomes

1

Description

Earth reaction force: According to Newton's third law, the earth reaction force is the force that the earth exerts on an object in contact with it. When a person is just standing, this force corresponds to the person's weight. When the body is moving, the ground reaction force increases due to acceleration forces. The ground reaction force has three components: fz, fx, and fy. • Vertical ground reaction forces Fz • vGRF is the largest component of the ground reaction force along the path. It is walking that results in forces greater than one body weight at each step. The vGRF curve consists of two peaks: the first peak (in the weight bearing phase) and the second peak (push off phase). This force is to support the body and prevent the body from falling during movement. The vertical ground reaction force represents the magnitude and pattern of vertical mechanical loading on the foot and is commonly used in the diagnosis of abnormal gait. The type of movement, the slope of the ground, the speed of movement, body mass, mass distribution, the material of the shoe, the material of the movement surface, and the mechanics of the foot are effective in the amount of this force. Ground reaction forces in the anterior-posterior direction F The forces of this component of the ground reaction are smaller than It is vertical and is about 25% of body weight. At the beginning of the stationary phase, this force causes the leading foot to brake or slip, and its value is negative in the first 50%, indicating that the person is pushed backwards, and at the end of the stationary phase, it is towards the front, and its value is positive. be And it makes progress forward.

Timepoint

immediate

Method of measurement

Using Kistler's Force plate device, we ask the child to walk on the force plate once with normal shoes, once

with thick sole medical shoes and another time with thin sole medical shoes. We measure the parameters of vertical forces of ground reaction, anterior, posterior and internal external forces of ground reaction which are recorded in the form of a diagram while walking in three test situations.

2

Description

- The amount of displacement of the center of pressure:
- Theoretical definition: the value of displacement of the result point of the earth's reaction force
- Applied definition: the number shown by the computer dynamic state device in centimeters related to the X and Y axes.

Timepoint

immediate

Method of measurement

Using the Kistler plate force plate device, we ask the child to walk on the force plate once with normal shoes, once with thick sole medical shoes and another time with thin sole medical shoes. We record the number shown by the computerized body dynamics device in centimeters related to the X and Y axes.

Secondary outcomes

empty

Intervention groups

1

Description

- First, using the foot posture index questionnaire (FPI-6), we perform a complete examination of the child's foot and determine its index. Before performing each step, the child walks with each of the shoes(with rigid sole, soft sole and regular shoe) for 5 minutes to adapt to it, and then enters the measurement phase. Using the Kistler force plate device, we ask the child to walk on the force plate once in a position with normal shoes. COP and the parameters of vertical ground reaction forces, anterior posterior and internal external forces of ground reaction during walking are measured and checked.

Category

Treatment - Devices

2

Description

Intervention group: • First, using the foot posture index questionnaire (FPI-6), we perform a complete examination of the child's foot and determine its index. Before performing each step, the child walks with each of the shoes for 5 minutes to adapt to it, and then enters the measurement step. Using the Kistler force plate device, we ask the child To walk on the force plate with thick sole medical shoes. • COP and parameters of vertical ground reaction forces, anterior posterior and internal external forces of ground reaction during walking are measured and checked.

Category

Treatment - Devices

3

Description

Intervention group: • First, using the foot posture index questionnaire (FPI-6), we perform a complete examination of the child's foot and determine its index. Before performing each step, the child walks with each of the shoes for 5 minutes to adapt to it, and then enters the measurement phase. Using the Kistler force plate device, we ask the child to walk on the force plane in the condition of thin-soled medical shoes. • COP and the parameters of the vertical ground reaction forces, anterior, posterior and internal external forces of the ground reaction during walking are measured and checked.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran university of medical sciences - department of othotics and prosthtics

Full name of responsible person

Behshid Farahmand

Street address

Madar Square, Shah Nazari St., Faculty of Rehabilitation Sciences ,Tehran ,Iran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 0947

Fax

+98 21 2222 0946

Email

farahmandb1@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Shah nazari st- Mother SQ- Rehabilitation sciences faculty Tehran Iran

City

Tehran

Province

Tehran

Postal code
1545913487

Phone
+98 21 2222 0947

Fax
+98 21 2222 0946

Email
farahmandb1@yahoo.com

Web page address
<http://www.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
Behshid Farahmand

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Orthopedics

Street address
Shahnazari st- Mother Sq- Rehabilitation science faculty Tehran Iran

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 0947

Email
farahmandb1@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Behshid Farahmand

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Orthopedics

Street address
Shahnazari st- Mother Sq- Rehabilitation science faculty Tehran Iran

City
Tehran

Province
Tehran

Postal code
11545913487

Phone
+98 21 2222 0947

Email
farahmandb1@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Behshid Farahmand

Position
Assistant Proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Orthopedics

Street address
Shahnazari st- Mother Sq- Rehabilitation science faculty Tehran Iran

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 0947

Email
farahmandb1@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

Not applicable	public
Data Dictionary	Under which criteria data/document could be used
Not applicable	The results of this research
Title and more details about the data/document	From where data/document is obtainable
The average data will be reported in the paper extracted from the research	contact with : farahmandb1@yahoo.com
When the data will become available and for how long	What processes are involved for a request to access data/document
The start of the access period after the publication of the article	Depending on the conditions of the journal, the results are printed
To whom data/document is available	Comments