

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effects of long term use of arch support foot orthoses on lower limb kinematics and kinetics during walking in children with flexible flat foot

Protocol summary

Summary

Foot orthoses are often used to correct altered gait patterns. Most of the previous studies investigated the immediate effects of foot orthoses on biomechanical variables during walking. The aim of the present study was to evaluate the long term use of arch support foot orthoses on lower limb kinematics and kinetics during walking in children with flexible flat feet. 15 children with flexible flat feet (age range between 9-11 years) as a experimental group will be used arch support foot orthoses for 4 months. In the control group foot orthoses will be used for 4 months. Walking kinematic and kinetics will be recorded by vicon camera systems and Kistler forceplatform before and after of 4 months. ANOVA repeated measure will be used for statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082235517N1**

Registration date: **2017-09-04, 1396/06/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-04, 1396/06/13

Registrant information

Name

AmirAli Jafarnezhadgero

Name of organization / entity

University of Mohaghegh Ardabili

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 0903

Email address

a.jafarnezhad@uma.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Mohaghegh Ardabili

Expected recruitment start date

2017-09-04, 1396/06/13

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of long term use of arch support foot orthoses on lower limb kinematics and kinetics during walking in children with flexible flat foot

Public title

Effects of long term use of arch support foot orthoses on lower limb kinematics and kinetics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age range between 9-12 years; Flexible flat feet; Male. Exclusion criteria: History of lower limb injury; History of surgery.

Age

From **9 years** old to **12 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil university of Medical Sciences

Street address

Ardabil province- Ardabil city-Ardabil university of medical sciences

City

Ardabil

Postal code

Approval date

2017-08-20, 1396/05/29

Ethics committee reference number

IR-ARUMS-REC-1396-90

Health conditions studied

1

Description of health condition studied

Flexible flat foot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

Walking kinematics

Timepoint

before and after 4 months

Method of measurement

Vicon cameras

2

Description

Walking kinetics

Timepoint

before and after 4 months

Method of measurement

Force platform

Secondary outcomes

1

Description

Ground reaction forces

Timepoint

before and after 4 months

Method of measurement

Forceplatform

Intervention groups

1

Description

Intervention group: 4 months use of arch support foot orthoses

Category

Rehabilitation

2

Description

Control group: long term use of placebo orthoses

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Schools

Full name of responsible person

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mohagheh Ardabili University

Full name of responsible person

AmirAli Jafarnejhadgero

Street address

Physical education and sport sciences department, Mohagheh Ardabili University, Ardabil, Iran,

City

Ardabil

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mohaghegh Ardabili University

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
Mohaghegh Ardabili University

Full name of responsible person
AmirAli Jafarnezhadgero

Position
Assistant professor/ Phd

Other areas of specialty/work

Street address
Ardabil province-Ardabil-Mohaghegh Ardabili University

City
Ardabil

Postal code

Phone
+98 45 3351 0903

Fax

Email
amiralijafarnezhad@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mohaghegh Ardabili University

Full name of responsible person
AmirAli Jafarnezhadgero

Position
Assistant professor/Phd

Other areas of specialty/work

Street address
Physical education and sport sciences department,
Mohaghegh Ardabili University, Ardabil, Iran,

City
Ardabil

Postal code

Phone
+98 45 3351 0903

Fax

Email
amiralijafarnezhad@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mohaghegh Ardabili University

Full name of responsible person
AmirAli Jafarnezhadgero

Position
PhD

Other areas of specialty/work

Street address
Ardabil province- Ardabil city- Mohaghegh Ardabili University

City
Ardabil

Postal code

Phone
+98 45 3351 0903

Fax

Email
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