

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of arch support insole in shoes and sandals on medial arch collapse in school_aged children with flexible flat foot during standing and walking

Protocol summary

Study aim

The effect of arch support insole in shoes and sandals on medial arch collapse in school_aged children with flexible flat foot during standing and walking

Design

A cross-over type clinical study that each participant will receive all the interventions of the study in one session and randomly. In this study, the data will be analyzed both statically (while standing) and dynamically (Mid stance and Heel off). To randomize the order of the tests (static or dynamic), the method of drawing lots by the patient (taking the envelope in the package from inside a basket) is used.

Settings and conduct

In this research, 40 children are selected non-randomly from those who refer to the technical orthopedic centers of Tehran and Karaj by easy and accessible sampling method

Participants/Inclusion and exclusion criteria

Inclusion criteria included: participants aged 7_11 with flexible flat foot and Foot Posture Index FPI ≥ 6 .
exclusion criteria included: any previous history of ligaments laxity based on Beighton test , Achill tendon contracture based on Silfverskiold test, neuromuscular problems, limb length discrepancies of 1/5 cm or greater , orthopedic disease, Functional abnormalities which can impair gait pattern, foot deformities such as hallux valgus, hallux rigidus, hammer toe, claw toe.

Intervention groups

A pair of shoes and sandals and arch support insole will be provided for each subject which is apt with their foot length

Main outcome variables

first toe dorsiflexion angle /MLA angle/Arch height index(AHI)/ ankle dorsiflexion angle/rear foot angle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230926059520N1**

Registration date: **2023-11-21, 1402/08/30**

Registration timing: **retrospective**

Last update: **2023-11-21, 1402/08/30**

Update count: **0**

Registration date

2023-11-21, 1402/08/30

Registrant information

Name

Sajedeh Haghghi Poodeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3226 7600

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of arch support insole in shoes and sandals on medial arch collapse in school_aged children with flexible flat foot during standing and walking

Public title

The effect of arch support insole in shoes and sandals on medial arch collapse in school_aged children with flexible flat foot during standing and walking

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

flexible flat foot

Exclusion criteria:

Age

From **7 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 Isfahan University of Medical Sciences

Street address

Hezar jarib Ave.

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-11-19, 1402/08/28

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.136

Health conditions studied

1

Description of health condition studied

flexible flat foot

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

arch support insole/sandal/shoe/age/gender/foot length/BMI

Timepoint

Measuring and collecting information before the start of tests

Method of measurement

Collecting patient information through personal information questionnaire, measuring body mass index through meters and scales

Secondary outcomes

1

Description

first toe dorsiflexion angle/MLA angle/Arch height index(AHI)/ankle dorsiflexion angle/rearfoot angle

Timepoint

The duration of each test is 2 minutes, with 5 repetitions and 2-minute breaks, the data obtained from the Mid stance and Heel off moments will be collected.

Method of measurement

Kinematic data will be collected using a Samsung, India (galaxy A71) mobile phone camera, with a frequency of 240 Hz and a resolution of 1920 x 1080 and 5 flat reflective markers with a diameter of 6 mm,

Intervention groups

1

Description

Intervention group: 1- Walking with bare feet 2- Walking with shoes 3- Walking with shoes with insoles 4- Walking with sandals 5- Walking with sandals with insoles.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Navide-salamat center

Full name of responsible person

Sajedeh Haghighi Poodeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Ebrahim Sadeghi Demneh

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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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

The findings are sent to scientific journals for publication.

When the data will become available and for how long

The findings are sent to scientific journals for publication.

To whom data/document is available

The findings are sent to scientific journals for publication.

Under which criteria data/document could be used

The findings are sent to scientific journals for publication.

From where data/document is obtainable

The findings are sent to scientific journals for publication.

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

The findings are sent to scientific journals for publication.

Comments

The findings are sent to scientific journals for publication.