Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of medial longitudinal arch support and UCBL in knee adduction moment arm in children with flexible flat foot.

Protocol summary

Study aim
The effect of medial longitudinal arch support and UCBL on the torque of the knee joint in children with flexible plantar fasciitis

Design
Clinical trial with parallel groups, one-way blind, randomized,

Settings and conduct
This study is a parallel clinical trial. Available sampling method is performed from people referring to the centers belonged to Isfahan University of Medical Sciences in 2020 for 3 months. After filtering from inclusion and exclusion criteria in the biomechanics laboratory of the Rehabilitation Faculty of Isfahan University of Medical Sciences, individuals are randomly divided into two intervention groups A and B and are scanned with a 3D scanner to make the sole of the foot. After applying the changes, the insole file is transferred to the 3D printer machine in order to make the insole.

Participants/Inclusion and exclusion criteria
1) Flexible flat foot with foot posture index above 9 on both feet 2) Range of age between 8-11 years 3) Genovalgum more than 6 degrees 4) Genovalgum less than 12 degrees (mild) 5) Do not use insoles and other orthoses in the past

Intervention groups
Subjects will participate in the study in two different modes of intervention (medial longitudinal arch support insole, with UCBL) and one mode without intervention in walking position.

Main outcome variables
knee adduction moment arm, medical insole with medial longitudinal arch support

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200516047459N1**
Registration date: **2020-10-03, 1399/07/12**
Registration timing: **retrospective**

Last update: **2020-10-03, 1399/07/12**
Update count: **0**

Registration date
2020-10-03, 1399/07/12

Registrant information

Name
Masoud Rafiaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 5043

Email address
ma.rafiaei@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-08-21, 1399/05/31

Actual recruitment start date
2020-05-21, 1399/03/01

Actual recruitment end date
2020-08-21, 1399/05/31

Trial completion date
2020-11-20, 1399/08/30

Scientific title
The effect of medial longitudinal arch support and UCBL in knee adduction moment arm in children with flexible flat foot.

Public title

The effect of two types of medical insoles on knee torque in children with flat feet

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Flexible flat foot with foot posture index above 9 on both feet Range of age between 8-11 years Genovalgum more than 6 degrees Genovalgum less than 12 degrees (mild) Do not use insoles and other orthoses in the past

Exclusion criteria:

Age

From **8 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants are in two groups and the type of insole is not known to them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Isfahan University of Medical Sciences

Street address

Hezarjerib

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2020-02-09, 1398/11/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.097

Health conditions studied

1

Description of health condition studied

flexible flat foot

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

knee adduction moment arm

Timepoint

Before and immediate after

Method of measurement

Force plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: subjects that use medical insole with medial longitudinal arch support

Category

Rehabilitation

2

Description

Intervention group: subjects that use UCBL insole

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Centers affiliated to Isfahan University of Medical Sciences

Full name of responsible person

Masoud Rafiaei

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Sponsors / Funding sources

1

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Name of organization / entity
Esfahan University of Medical Sciences
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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information is confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Print article

When the data will become available and for how long

9 months

To whom data/document is available

writers

Under which criteria data/document could be used

Documentation will be available if used in future studies.

From where data/document is obtainable

corresponding author

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

e-mail

Comments