

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Functional and radiographic comparison of subtalar arthroereisis and lateral calcaneal lengthening in surgical treatment of flexible flatfoot in children

Protocol summary

Study aim

1- Determination and comparison of patients' mean pain score based on VAS 12 months after surgery 2- Determination and comparison of mean pain score of patients based on VAS scale before and 12 months after subtalar arthroereisis surgery 3- Determination and comparison of mean pain score of patients based on VAS scale before and 12 months after Lateral calcaneal lengthening surgery 4- Determination and Comparison of Frequency Distribution of Clinical Evaluation Indices Based on MOSCA Criterion 12 Months after Surgery in Patients in Two Groups

Design

A clinical trial with a parallel-group, the single-blind, block randomized, sample size of 25 patients

Settings and conduct

Surgery was performed at a Kashani hospital by a surgeon.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction , children with idiopathic symptomatic flat foot who were treated by arch support for at least 6 months of medical treatment. Exclusion criteria: Patients with underlying diseases such as metabolic bone disease, CP, myelomeningocele, arthrogryposis, history of trauma, carcinoma and parathyroid gland disease.

Intervention groups

In this study, 25 children with a flexibly flat foot, 8-14 years old, from 2016 to 2017 are candidates for subtalar arthroereisis surgery and will be prospectively evaluated. These children were treated medically before surgery for subtalar arthroereisis and lateral calcaneal lengthening.

Main outcome variables

Signs of subtalar arthroereisis and lateral calcaneal lengthening VAS criteria Mosca criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180823040853N1**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **retrospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Mohammad Ali Tahririan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3972 6873

Email address

tahririan@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Functional and radiographic comparison of subtalar arthroereisis and lateral calcaneal lengthening in surgical treatment of flexible flatfoot in children

Public title

Functional and radiographic comparison of subtalar arthroereisis and lateral calcaneal lengthening in surgical treatment of flexible flatfoot in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study, Children with idiopathic symptomatic flat feet who have been supported by arch support for at least 6 months of medical treatment

Exclusion criteria:

underlying bone metabolic disease cerebral palsy myelomeningocele arthrogryposis parathyroid problems

Age

From **8 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization method was used and we use computer generated randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-12-22, 1398/10/01

Ethics committee reference number

IR.MUI.MED.REC.1398.415

Health conditions studied

1

Description of health condition studied

pediatric flexible flat foot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

Reduce and improve skeletal muscle pain

Timepoint

Medical treatment at 6 months before surgery and AP and lateral foot and ankle radiographs in standing position before and 12 months after surgery

Method of measurement

MOSCA, VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Twenty-five children with a flexible flat foot candidate for subtalar arthroereisis surgery will be enrolled in the study and will be prospectively evaluated. These children were treated medically before surgical treatment. All patients are supine and under general anesthesia. A 2cm incision is made in the lateral malleolus at the site of the anteroinferior, and the calcaneo-stop screw is then inserted into the heel bone at the entrance of the tarsus sinus to limit the movements of the talus. It is built to maintain the physiological and anatomical structure of the talus and calcaneus. Surgery will be performed at Kashani Hospital and all by a surgeon.

Category

Treatment - Surgery

2

Description

Twenty-five children with flexible flatfoot are candidates for Lateral calcaneal lengthening surgery. These children were treated medically before surgical treatment. All

patients were supine and under general anesthesia. A 3 cm incision was made at the anterior third of the heel bone, and between the anterior and middle articular surface of the calcaneal osteotomy was performed, followed by an allograft at the osteotomy site.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

kashani Hospital

Full name of responsible person

Mohammad Ali Tahririan

Street address

Kashani Hospital, Ayatollah Kashani Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Mortzavi

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vice chancellor of Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan

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dean@med.mui.ac.ir

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

Mohammad Ali Tahririan

Position

Associate Professor of Pediatric Orthopedics
Department of Orthopedic Surgery, School of Medicine Ka

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Ali Tahririan

Position

Associate Professor of Pediatric Orthopedics
Department of Orthopedic Surgery, School of Medicine Ka

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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

No more information

Study Protocol

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

Statistical Analysis Plan

Not applicable

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