

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### Evaluation the effect of insole with longitudinal arch support on foot and ankle kinematics in children with flexible flat foot who have undergone subtalar arthroeresis

#### Protocol summary

##### Study aim

Evaluation the effect of insole with longitudinal arch support on foot and ankle kinematics in children with flexible flat foot who have undergone subtalar arthroeresis

##### Design

Clinical trial without control group, Single blind, Sample size of 10 patients, Our intervention in this study is insole with medial longitudinal arch support.

##### Settings and conduct

this test is performed in the research center of Isfahan faculty of sciences and rehabilitation and our intervention in the test is insole with medial longitudinal arch support that its material is soft foam. in this test, biomechanics of the foot and ankle are measured before and after the use of medical insole.

##### Participants/Inclusion and exclusion criteria

Entry condition: 1. age between 7 to 18 2. has flexible flat foot 3. undergone Arthroeresis surgery 4. a minimum of 6 months and maximum of 3 years have passed since the surgery condition of non-entry 1. flat foot due to neuromuscular, neurological diseases 2. history of lower limb trauma and any foot surgery 3. Existence of other deformities in the lower limbs

##### Intervention groups

the Sampling method is based on the available sampling method and among those referred to the orthopedic clinic of kashani hospital. the sample size is 10 children with flexible flat feet after arthroeresis surgery. the intervention group includes 10 patient with flexible flat foot who undergone Surgery and receive medical insole interventions. there is no control group in this study.

##### Main outcome variables

kinematics of the joints of the feet and ankles of children while walking.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211030052916N1**

Registration date: **2021-11-28, 1400/09/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-28, 1400/09/07**

Update count: **0**

##### Registration date

2021-11-28, 1400/09/07

##### Registrant information

##### Name

Amirhossein Zare

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-11, 1400/08/20

##### Expected recruitment end date

2021-12-01, 1400/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluation the effect of insole with longitudinal arch support on foot and ankle kinematics in children with flexible flat foot who have undergone subtalar arthroeresis

**Public title**

Evaluation the effect of insole on the feet of operated Children

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

A child between the ages of 7 to 18 with flexible flat foot who has undergone subtalar arthroeresis Surgery minimum of 6 months and maximum of 3 years from the surgery

**Exclusion criteria:**

Flat foot caused by neurological, neuromuscular, dystrophic and hyperlaxis diseases history of lower limb trauma and any foot surgery Angular and rotational deformities of the lower limbs during walking Existence of any other pathology such as tarsal coalition, vertical talus, Skew foot, Accessory navicular bone

**Age**

From **7 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**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**

Hezarjari Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2021-05-08, 1400/02/18

**Ethics committee reference number**

IR.MUI.NUREMA.REC.1400.015

**Health conditions studied****1****Description of health condition studied**

Flexible flat foot

**ICD-10 code**

M21.40

**ICD-10 code description**

Flat foot [pes planus] (acquired), unspecified foot

**Primary outcomes****1****Description**

Percentage of kinematic effect of insole on children undergoing Arthroeresis surgery

**Timepoint**

Biomechanical measurement of the foot before and after using the insole

**Method of measurement**

Visual 3D Software

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: For each patient, a pair of medical insoles made of soft foam, which the patient steps on and walks with during the test. For testing each patient, a 2.5 hour back session was provided and these medical insole were of prefabricated type and were provided by technical orthopedic clinics.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Musculoskeletal center of the faculty of rehabilitation sciences

**Full name of responsible person**

Doctor Ebrahim Sadeghi Demneh

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Doctor Shaghayegh haghjoy javanmard  
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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**  
Doctor Saeed Forghany  
**Position**  
Professor

**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Province**

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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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Some of the tested data related to patients foot and ankle kinematics can be extracted. Patient personal information is not shared.

**When the data will become available and for how long**

After publishing the article

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

in addition to academic researchers in the field of flexible flat foot and a variety of treatment methods, Statistical analyzer for activity with Shapirolc and SPSS software and t-test study should be aware of the information and data. the main condition for data delivery is not making the data available to the public.

**From where data/document is obtainable**

Principal executor and supervisor of research project

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

By emailing the project manager or instructor Dr Saeed Forghany - saeed\_forghany@yahoo.co.uk

**Comments**