

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of gait plate insole and lateral sole wedged shoes on foot progression angle in children with in-toeing gait

Protocol summary

Study aim

Comparison the effect of gait plate insole and lateral sole wedged shoes on foot progression angle in children with in-toeing gait

Design

Randomized controlled trial, two parallel groups with no blinding, 30 patient

Settings and conduct

This study is being conducted at the rehabilitation faculty of Iran University of medical science. Rotational profile tests are performed to determine the cause of in-toeing gait. The type of intervention (gait plate insole/shoe with lateral sole wedge) will be selected randomly. Children are asked to walk on the scanner plate by self selected speed with and without intervention. All tests will be repeated 5 times to determine an average of the angle of gait. Children will be asked to use and walk with their intervention (gait plate insole/shoe with lateral sole wedge) for 4 weeks. Walking test with and without intervention will be repeated after 4 week similar to previous tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- angle of gait less than -3 2- positive rotational profile tests 3- anteversion more than 70 degree exclusion criteria: 1- severe deformity that need surgery 2- history of surgery on lower limb 3-history of fracture in lower limb 4- history of using orthopedic shoes or braces 5- neuromuscular and neurological diseases 6- history of deformities that effects angle of gait such as club foot and DDH 7- intoeing because of metatarsus adductus or internal tibial torsion

Intervention groups

first intervention- gait plate insole second intervention- shoe with lateral sole wedge

Main outcome variables

Angle of gait

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140219016643N8**

Registration date: **2020-07-22, 1399/05/01**

Registration timing: **retrospective**

Last update: **2020-07-22, 1399/05/01**

Update count: **0**

Registration date

2020-07-22, 1399/05/01

Registrant information

Name

Behshid Farahmand

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

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farahmand.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-27, 1398/09/06

Expected recruitment end date

2020-04-25, 1399/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision the effect of gait plate insole and lateral sole wedged shoes on foot progression angle in children with in-toeing gait

Public title

Comparision the effect of gait plate insole and lateral sole wedged shoes on foot progression angle in children with in-toeing gait

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

less than -3 degree angle of gait positive rotational profile tests more than 70 degree anteversion

Exclusion criteria:

sever deformities candidate if surgery surgical history on lower limbs fractures history on lower limbs using orthotic devices or orthopedic shoes history neurologic or neuromuscular disease deformities on lower limb history such as club foot or ddh intoeing because of metatarsus adductus or internal tibial torsion

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be asked to pick up a card (treatment on it) from a box (chance of choosing any treatment is equal).

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

Iran University of Medical Sciences

Street address

Mother Square, Abkar Shahnazari Street, Madadkaran Street, Faculty of Rehabilitation Sciences

City

tehran

Province

Tehran

Postal code

1545913487

Approval date

2019-11-04, 1398/08/13

Ethics committee reference number

IR.IUMS.REC.1398.805

Health conditions studied

1

Description of health condition studied

intoeing gait in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

effectiveness of orthotics on angle of gait

Timepoint

before intervention, immediately after intervention, after 4 weeks of using the intervention

Method of measurement

using RS scan to evaluate angle of gait

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: gait plates insole. This insole is made from a cast of the child's feet in a subtalar neutral position and 3-mm diameter thermoplastic sheet. Distally the insole is extended behind the first metatarsal head medially, and at an angle of 45 degrees beyond the fourth and fifth metatarsal heads laterally.

Category

Treatment - Devices

2

Description

second Intervention group: Shoe with lateral sole wedge. This shoe is made of leather with rubber outsole. 3 mm rubber wedge is placed in the forefoot area at the lateral side of the outsole.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation Sciences of Iran University

Full name of responsible person

Seyyed Shahab Aldin Parian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Research@iums.ac.ir

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Behshid Farahmand

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for updating data

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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

Comparison the effect of gait plate insole and lateral sole wedged shoes on foot progression angle in children with in-toeing gait

When the data will become available and for how long

The start access is determined according to the law of the journal which the article is submitted

To whom data/document is available

Accessibility for all people

Under which criteria data/document could be used

Do not consider a particular item

From where data/document is obtainable

Contact by e-mail of corresponding author

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

If there is no precautionary statement from the journal which the article is printed, with contact by e-mail of corresponding author, information will be sent to the requesting person within less than one month

Comments