

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of gait plate insole and medial-wedge insole on balance and angle of gait of the in-toeing child

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of the effect of gate plate insole and medial-wedge insole on balance and angle of gait of in-toeing child

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Design

The clinical trial with a sample size of 30 children, two intervention groups, With parallel groups, triple blinded, randomized by block randomization method.

Registrant information

Name

Farzaneh Manouchehri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

Children are randomly divided into two groups. For the first group, the gate plate insole and the second group, the medial-wedge insole are designed and made. The velocity and displacement of the center of pressure and the angle of gait are measured by force plate and motion analysis system before intervention and one month after intervention in Shiraz Rehabilitation School, respectively. Subjects, researcher and statistical analyst are not aware of the type of intervention assigned.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Angle of gait less than -3 degrees, in-toeing gait due to excessive femoral anteversion and internal tibia torsion Exclusion criteria: In-toeing gait due to metatarsus adductus, severe deformities in lower limbs, history of surgery or fracture in lower limbs

Expected recruitment start date

2021-02-14, 1399/11/26

Expected recruitment end date

2021-09-21, 1400/06/30

Intervention groups

The clinical trial has two groups. The children of the first group will receive a gate plate insole and the second group will receive a medial-wedge insole.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Center of pressure displacement; velocity of center of pressure displacement; angle of gait

Trial completion date

empty

General information

Scientific title

Comparison of the effect of gait plate insole and medial-wedge insole on balance and angle of gait of the in-toeing child

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210419051014N1**

Registration date: **2021-06-18, 1400/03/28**

Public title

The effect of gait plate insole and medial-wedge insole for children with in-toeing gait

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pediatric population with an intoed gait In-toeing gait due to excessive femoral anteversion (internal rotation of the hip greater than 70 degrees) In-toeing gait due to internal tibia torsion (negative values of thigh-foot angle) Angle of gait less than -3 degrees Being 3 to 10 years old

Exclusion criteria:

In-toeing gait due to Cerebral Palsy In-toeing gait due to metatarsus adductus Severe deformities in lower limbs, for example, clubfoot, congenital hip joint dislocation, equinus of the foot and congenital flat foot History of surgery or fracture in lower limbs Neurological (Cerebral Palsy and Charcot Marie Thoth) and neuromuscular diseases Using medical shoes and orthoses Lack of children's and/or parents' consent to cooperate

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. This method is used to balance the number of samples assigned to each of the study groups. In this study, considering that we have two groups, blocks with size of 4 are used. The randomization tool is used is random allocation software that is able to generate random sequences by block randomization method. Group assignment is hidden in dark, sealed envelopes that are numbered consecutively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of that participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Subjects and researchers are not aware of the type of insole allocated. The person analyzing the data is unaware of the study and examines the data in general.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Science, Kodakyar Dead End., Daneshjo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.USWR.REC.1399.160

Health conditions studied

1

Description of health condition studied

Intoeing gait pattern

ICD-10 code

R26.8

ICD-10 code description

Other abnormalities of gait and mobility

Primary outcomes

1

Description

Center of pressure displacement

Timepoint

Measurement of the displacement of center of pressure at the beginning of the study (before the intervention) and one month after using the gate plate insole or medial-wedge insole

Method of measurement

Force plate instrument

2

Description

Velocity of center of pressure displacement

Timepoint

Measure the velocity of center of pressure displacement at the beginning of the study (before the intervention) and one month after using the gate plate insole or medial-wedge insole

Method of measurement

Force plate instrument

3

Description

Angle of gait

Timepoint

Measure the angle of gait at the beginning of the study (before the intervention) and one month after using the gate plate insole or medial-wedge insole

Method of measurement

Motion analysis system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The first group will receive a gate plate insole. It is a rigid plastic shell that covers the plantar area, with an extension beyond fourth and fifth metatarsal heads. Gate plate insoles were made-to-order and customized to the foot of each child. Children should use the insole for at least 4 hours a day for a month.

Category

Treatment - Devices

2

Description

Intervention group2: The second group receive a medial-wedge insole. The medial-wedge insole with a height of 5 mm and an arch support extending from heel to toe made of ethylene-vinyl acetate were made-to-order and customized to the foot of each child. Children should use the insole for at least 4 hours a day for a month.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavanmehr Technical Orthopedic Clinic

Full name of responsible person

Majid Manochchri

Street address

Tavanmehr Technical Orthopedic Clinic, Shirazmehr Medical Complex, Jamali St, Mullasadra St,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khorram Khorshid

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webmaster@uswr.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abas Rezaianzade

Street address

School of Rehabilitation Sciences, Abivardi1 St, Chamran Blvd

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Shiraz

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Phone

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Email

Rehab@Sums.ac.ir

Grant name

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

Yes

Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
50

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
University of social welfare and rehabilitation sciences

Full name of responsible person
Farzaneh Manouchehri

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Orthotics and prosthetics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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