

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of gait plates on spatio-temporal parameters of gait and foot progression angle of in-toeing gait children

Protocol summary

Study aim

The aim of this study is investigating the effect of "gate plate" insole on "foot progression angle" and "temporal-spatial parameters" of children with intoeing gait over a period of one month. In this study the positive and negative effects of the gate plate insole on the gait parameters, in addition to the foot progression angle, will be measured.

Design

Clinical trial with control group, without blinding, randomized. Coin toss was used for randomization.

Settings and conduct

The research will be conducted in children's medical centers. The child will walk with shoes on a paper walk way to record footprints. The child will be filmed walking at the same time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 3 to 10 years old! Intoeing gait pattern on both feet! Foot progression angle is less than -3 degrees! Intoeing gait pattern due to increased or permanent internal tibial torsion or increased or permanent femoral anteversion or both Exclusion criteria: Having or a history of severe motor changes or deformities in the lower extremities that affect gait! History of fracture and surgical treatment of the lower limb. Surgical treatment such as bone surgery, osteoarticular surgery or neuromuscular tissue surgery! Intoeing for reasons that require surgery

Intervention groups

The intervention group includes children 3 to 10 years old who have intoeing. The intervention group will be given a gait plate insole to investigate its effect on gait parameters.

Main outcome variables

The effect of the gate plate insole on the forward angle of the foot will be determined. The effect of the gate plate insole on the temporal-spatial parameters of walking will be determined.

General information

Reason for update

The method of randomization was changed from block to simple because according to the researcher, this method reduces the possibility of biasing the results. The main condition of not entering the study before randomization - English was added because it was previously forgotten. Explanation about concealment: None. Because this study was not blinded. The main purpose of the study was changed to treatment because it is more consistent with the research topic. The tick of the patient recruitment is terminated option is activated because the patient recruitment has been terminated. The start and end dates of the realized sick leave were added. The trial termination date was added.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210830052340N1**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **prospective**

Last update: **2022-07-10, 1401/04/19**

Update count: **1**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Vahid Pourmoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

2021-09-23, 1400/07/01

Actual recruitment end date

2022-02-09, 1400/11/20

Trial completion date

2022-03-16, 1400/12/25

Scientific title

The effect of gait plates on spatio-temporal parameters of gait and foot progression angle of in-toeing gait children

Public title

The effect of gait plates on in-toeing gait children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 3 to 10 years old intoeing gait Pattern in both feet foot Progression angle less than 3 degrees intoeing gait Pattern due to increased or permanent internal tibial torsion or increased or permanent femoral anteversion or both

Exclusion criteria:

Participants were excluded from the study if 1) they suffered or had suffered from motor alterations or serious deformities in the lower limb that would affect gait, such as infantile cerebral paralysis, neuromotor alterations in the lower limb, osteochondrosis with serious sequelae, congenital luxation of the hip, equinus foot, rocker-bottom foot, congenital convex flatfoot, clubfoot, and serious varus forefoot had been surgically treated in the lower limb (bone surgery, osteoarticular surgery, or surgery of the neuromuscular tissue) presented with in-toeing requiring surgical treatment. Lack of consent of the child and parents to continue cooperation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and descriptions of each method: Simple randomization Randomization unit: individual Randomization tool: Coin toss, face for the intervention group and behind for the control group How to build a random sequence: central randomization Explanation about allocation concealment: N/A

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

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

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kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2021-08-25, 1400/06/03

Ethics committee reference number

IR.USWR.REC.1400.123

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

intoeing gait

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

foot progression angle

Timepoint

Measure the foot progression angle immediately and one month after using the gait plate insole

Method of measurement

Measure the midline of the shoeprints on the paper aisle

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children who will wear a gate plate for a month. The gate plate insole is a rigid thermoplastic insole made of polypropylene sheet with a thickness of 3 mm, which is placed in the shoe and covers the entire sole of the foot up to the metatarsal heads.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalifard rehabilitation

Full name of responsible person

Habib Afzalifard

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Thirty meters street, Next to Negin Hotel

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greatlack@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Vice President for Research and Technology

Street address

kodakyar Ave., daneshjo Blvd.,Evin

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Grant name

Grant code / Reference number

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

No

Title of funding source

Master degree Proposal

Proportion provided by this source

1

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

Vahid Pourmoghadam

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Orthopedics

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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