Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of night orthosis on foot and ankle biomechanics in children with flexible flatfoot and gastro-soleus stiffness: Based on Randomized clinical trial

Protocol summary

Study aim
Determining the effectiveness of night orthosis on the gastrosoleus stiffness and kinematics during walking in children with flexible flatfoot and gastro-soleus stiffness

Design
A randomized clinical trial with parallel groups and control group, one-way blinded, on 20 patients. Statistical software was used for randomization

Settings and conduct
This study will be performed at Isfahan University of Medical Sciences. biodex isokinetic device and motion analysis were used

Participants/Inclusion and exclusion criteria
children with flexible flatfoot and gastrosoleus stiffness and without any problems or trauma to the lower limb

Intervention groups
The control group gastrosoleus muscle stretching exercise and the intervention group night orthosis in addition to gastrosoleus muscle stretching exercise are given

Main outcome variables
ankle passive dorsiflexion range of motion; gastrosoleus stiffness; pain; Quality of Life; foot and ankle kinematic

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210712051853N1**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date
2021-08-09, 1400/05/18

Registrant information

Name
somaieh payehdar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of night orthosis on foot and ankle biomechanics in children with flexible flatfoot and gastro-soleus stiffness: Based on Randomized clinical trial

Public title
Evaluation of the effect of night orthosis on foot and ankle biomechanics in children with flexible flatfoot and gastro-soleus stiffness

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 7 to 14 years Have symptomatic flexible flatfoot and gastro-soleus stiffness Normal BMI base on sex and age Pain parameter score of at least 1

Exclusion criteria:

Any problems or trauma to the lower extremities Previous Achilles tendon surgery Abnormal ankle bony prominence Inflammatory and / or infectious arthritis Any internal or metabolic disorders Neurological and musculoskeletal problems lower limb length discrepancy Use of any foot orthoses and the calf muscles stretching Any injury or pathology of the foot, knee, hip and/or back

Age

From **7 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

This feature helps us to equalize the size of all blocks in cases where intermediate analyzes are required during the sampling process. In this two-group clinical trial where the size of the blocks is equal, we will have 10 subjects in the intervention group and 10 subjects in the control group. Random allocation software is used, which in addition to simple randomization, can produce Random sequences that are block-making. For allocation concealment, which refers to the method used to execute random sequences on study participants so that the assigned group is not known before the individual is assigned. The opaque sealed envelopes in random sequences were used. In this method, each of the random sequences created is recorded on a card, and the cards are placed in the letter envelopes in order. To maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lid of the letter envelopes is glued and placed inside the box, respectively. At the beginning of the registration of the subjects, according to the order of entry of the eligible participants, one of the envelopes will be opened to determine the assigned group of the participant.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a one-way blinded study and participants will be blinded to the type of treatment that can be exercise or exercise with orthosis

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

Mir Bagheri dormitory, Isfahan University dormitories,Hezarjarib St.

City

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Province

Isfehan

Postal code

8174643461

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.008

Health conditions studied

1

Description of health condition studied

flexible flatfoot with gasrtosoleus stiffness

ICD-10 code

M21.40

ICD-10 code description

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

Primary outcomes

1

Description

change of the ankle passive dorsiflexion range of motion

Timepoint

at the beginning of the study, three months later and finally two weeks after the second measurement

Method of measurement

Biodex iskinetics and goniometer

2

Description

Gastrosoleus muscle stiffness

Timepoint

At the beginning of the study, three months later and finally two weeks after the second measurement

Method of measurement

Biodex iskinetics

3

Description

gait Kinematic

Timepoint

At the beginning of the study, three months later and finally two weeks after the second measurement

Method of measurement

motion analysis

Secondary outcomes

1

Description

pain

Timepoint

At the beginning of the study, three months later and finally two weeks after the second measurement

Method of measurement

Wong-Baker FACES scale

2

Description

Quality of Life

Timepoint

At the beginning of the study, three months later and finally two weeks after the second measurement

Method of measurement

Pediatric Quality of Life Inventory

Intervention groups

1

Description

Intervention group: Night orthoses are made of similar 5 mm polypropylene in two pieces, hinged ankle joint, with an extension in the popliteal area and without a joint for the knee, So, the knee will be straight at night and the gastrocnemius muscle will be stretched effectively by dorsiflexion of the ankle joint. The hinge ankle joint of the orthosis is adjusted at the angle of the maximum amount of tolerable dorsiflexion for each subject (that it does not cause pain or discomfort). A goniometer is placed on the ankle joint to measure the dorsiflexion angle. The ankle is placed at the maximum tolerable dorsiflexion angle for maximum stretching on the gastro-soleus complex Using the orthosis elastic band. In this way, the degree of gradual increase of the dorsiflexion angle is recorded on the relevant forms by participants or their parents at night when the orthosis is worn. A hole is placed under the hindfoot to determine the full connection between the heel and the orthosis plate. Therefore, we can be ensured the complete connection of the heel in orthosis and the placement of the subtalar joint in the neutral position.

Category

Rehabilitation

2

Description

Control group: The participants will be instructed to do calf muscles eccentric stretching program for 12 weeks which included five sessions per week with each session containing three stretches performed for five sets of 30 seconds at their maximum tolerance level of stretch. To perform the calf muscles eccentric stretching program, from an upright body position and standing on one leg on the edge of the step and next to the wall (Where the subject can restore balance by hand if needed), all body weight will be placed on the forefoot and the ankle joint gone to plantar flexion, the calf muscle will be loaded by having the participant lower the heel beneath the forefoot toward the ankle plantar flexion position.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric orthopedic specialist office

Full name of responsible person

Dr. Mohammad Ali Tahririan

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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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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
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Latest degree
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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
Yes - There is 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
Yes - There is 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
Not applicable
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
The start of the access period is 6 months after the results are printed

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only to compare documents in similar studies

From where data/document is obtainable

sahar.paydar@gmail.com

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

The demand must be at least 6 months after the results are published

Comments