Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the Immediate Effect of Using a Heel Wedge with Three Different Heights on Knee Hyperextension Caused by Joint Hypermobility.

Protocol summary

Study aim
Determining the effect of the heel wedge on genurecurvatum caused by hypermobility
Design
The study is a single group, phase 2, clinical trial that examines the effect of three different heel heights on a group of 15 children with knee hyper-extension.
Settings and conduct
Location of the study: Two elementary schools, one for girls and one for boys, in District 11 of Tehran; study population: 15 individuals; type of blinding: there will be no blinding in this study.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 5 to 10 years, suffering from knee hyperextension greater than 10 degrees but less than 20 degree, with a Beighton score greater than 6. Exclusion criteria: Individuals with deformities in the lower limb joints or spine, pain in the lower limb joints within the past two weeks, anterior or posterior cruciate ligament tears, suffering from lower limb injury in the last six months, Individuals with a body mass index (BMI) above 25.
Intervention groups
Children will wear special shoes with the following heel heights: Once without a wedge Once with a 15 mm heel height Once with a 25 mm heel height Once with a 35 mm heel height at the heel.
Main outcome variables
Temporal-Spatial Variables of Walking; Kinematics of the Ankle, Knee, and Hip Joints; Kinetics of the Ankle, Knee, and Hip Joints; Muscle Activity Patterns of the Knee.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240906062959N1**
Registration date: **2024-12-11, 1403/09/21**
Registration timing: **prospective**

Last update: **2024-12-11, 1403/09/21**
Update count: **0**
Registration date
2024-12-11, 1403/09/21

Registrant information
Name
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-01-13, 1403/10/24
Expected recruitment end date
2025-03-14, 1403/12/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Immediate Effect of Using a Heel Wedge with Three Different Heights on Knee Hyperextension Caused by Joint Hypermobility.

Public title
Investigating the Effect of Heel Wedges on Gait Correction in Children with Joint Hypermobility

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
5 to 10 years old children children With knee hyperextension greater than 10 degrees and less than 20 degrees Children with a Beighton score greater than 6
Exclusion criteria:
Individuals with deformities in the lower limb joints and spine individuals who have experienced pain in the lower limb joints in the past two weeks individuals with anterior and posterior cruciate ligament tears individuals who have suffered a lower limb injury in the last six months individuals with a body mass index (BMI) above 25 Children under 5 years old and over 10 years old
Age
From **5 years** old to **10 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **15**
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 the University of social welfare and rehabilitation
Street address
University of Rehabilitation Sciences and Health, Kudakiar Dead End, Daneshju Boulevard, Velenjak
City
tehran
Province
Tehran
Postal code
1985713871
Approval date
2024-11-03, 1403/08/13
Ethics committee reference number
IR.USWR.REC.1403.183

Health conditions studied

1

Description of health condition studied
joint hyper mobility , genurecurvatum
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
spatio-temporal parameters
Timepoint
The immediate effect is examined immediately after the intervention
Method of measurement
The calculation of spatial-temporal variables is performed using data obtained from the Vicon motion capture system (Vicon Motion Systems, Oxford, UK) with six cameras operating at a frequency of 120 Hz. The distance and time for each of the subphases of walking will be calculated through the software

2

Description
Kinematics of the Ankle, Knee, and Hip Joints
Timepoint
The immediate effect is examined immediately after the intervention
Method of measurement
The calculation is performed using data obtained from the Vicon motion capture system (Vicon Motion Systems, Oxford, UK) with six cameras operating at a frequency of 120 Hz. This is done in such a way that after defining each segment, the variations in joint angles are calculated using software

3

Description
kinetics of the Ankle, Knee, and Hip Joints
Timepoint
The immediate effect is examined immediately after the intervention
Method of measurement
The torque generated around each joint is calculated using the data obtained from the force plate, which involves the ground reaction force multiplied by its distance from the center of the joint

4

Description
Muscle Activity Pattern of the Knee Joint
Timepoint
The immediate effect is examined immediately after the intervention
Method of measurement

Muscle activity is measured using a 48-channel Aktos electromyography device manufactured by Myon, with bipolar surface electrodes synchronized with the force plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Shoes without heel and shoes with three different heights of 15 mm, 25 mm, and 35 mm, heel wedge. For each child in the intervention group, a pair of long boots made of synthetic leather will be prepared according to the length of their feet. The shoe design will incorporate a conventional orthopedic insole made of polyurethane that supports the longitudinal arch inside the shoe, and specially designed wedges for each size will be used in the external sole of the shoe. The design of the wedges will ensure that they end before the metatarsal heads, specifically at the break point of the shoe at the toe, reaching their minimum diameter. The wedges will be constructed with heights of 15 mm, 25 mm, and 35 mm at the heel. The height of the wedges on both the inner and outer sides will be equal to each other up to the end, starting from the heel and decreasing as it approaches the front of the foot, finishing before reaching the metatarsal heads. The design and construction of the wedges will be done using a molding device tailored to the shoe size by an orthotics specialist. Three heights for each size will be prepared that can be attached to the midsole of the shoe using double-sided tape. The children will be asked to wear the special shoes once without a wedge, once with a 15 mm heel wedge, once with a 25 mm heel wedge, and once with a 35 mm heel wedge. It is important to note that the order of wearing the shoes will be in a randomized block design. After assigning the type of height, measurements for each height will be taken with three repetitions. Each child will wear the shoes and the different heights of heel wedges in the specified order, and the walking test will be repeated three times for each height. A 20-second rest period will be provided between each intervention to prevent fatigue

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Boy and Girls' Schools in District 11, Tehran

Full name of responsible person

Maryam Hashemzadeh

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University of Rehabilitation Sciences and Health, Kudakiar Dead End, Daneshju Boulevard, Velenjak

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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

Dr Mohamad Saeed Khanjani

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Maryam Hashemzadeh

Position

Ph.D candidate

Latest degree
Master
Other areas of specialty/work
orthotics and prosthetics
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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