Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of the effects of lateral wedges with and without hip and trunk muscles strengthening on balance in young people with genu varum

Protocol summary

Study aim
Comparison of the effect of lateral wedge with and without hip and trunk muscle strengthening on balance of young people with genu varum

Design
Two arm parallel group without blinding randomised trial of 40 patients

Settings and conduct
Study of balance with force plate during standing walking and jumping at laboratory of Shahid Beheshti of Medical Sciences.First he or she stands with two legs and with open eyes on forceplate for 1 minute. This test is repeated 3 times. Then walks in a specific path with bare feet so that the dominant limb is placed on the force plate. This test is repeated 3 times. Finally, he or she performs the jump-landing. Before performing the task to normalize the vertical height of the jump, it is necessary to calculate 50% of the maximum jump height. Then he or she stands behind the mark that is determined and the person jumps with two legs and the 50% maximum jump mark is touched with one hand and with the dominant leg lands single leg for 20s. This test is repeated 3 times. Subjects are divided into two groups of control and intervention and one month later these tests are repeated again and data related to static and dynamic balance indices are compared.

Participants/Inclusion and exclusion criteria
inclusion criteria 1.with bilateral genu varum at 18-40 ages exclusion criteria 1.other lower extremity deformities 2. history of corrective surgery of spine and lower extremity, fracture 3.vision, ear, balance, cognitive problems 4.professional athlete 5.walking with auxillary devises

Intervention groups
group 1 using lateral wedge without exrecise . group 2 using lateral wedge with hip and trunk muscle strengthening exercises.

Main outcome variables
velocity and displacement of foot pressure center in anterior-posterior, medial-lateral, ground reaction force and time to stabilization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221103056387N1**
Registration date: **2023-04-03, 1402/01/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-03, 1402/01/14**
Update count: **0**

Registration date
2023-04-03, 1402/01/14

Registrant information

Name
Nafiseh Shahri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4495 2297

Email address
shahri.nafiseh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effects of lateral wedges with and without hip and trunk muscles strengthening on balance in young people with genu varum

Public title

the effects of lateral wedges with and without hip and trunk muscles strengthening on balance in young people with genu varum

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

genuvarum deformity bilateral deformity age between 18-40

Exclusion criteria:

other deformity such as anteversion corrective surgery of the spine and lower extremity Balance and cognitive problems, ear, vision and neuromuscular skeletal need help for walking and use auxiliary Equipment history of fracture and trauma in last year professional Athlete

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No.21, Javaherian alley, Motahari street, Central Payambar street, Tehran

City

Tehran

Province

Tehran

Postal code

1471844855

Approval date

2022-06-26, 1401/04/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.149

Health conditions studied

1

Description of health condition studied

genu varum (bow leg)

ICD-10 code

M21.169

ICD-10 code description

Varus deformity, not elsewhere classified, unspecified knee

Primary outcomes

1

Description

velocity and displacement of pressure center of foot, ground reaction force and time to stabilization

Timepoint

at the begining of study (before of treatment) and 1 month later

Method of measurement

forceplate

Secondary outcomes

empty

Intervention groups

1

Description

"Control group:" using lateral wedge in shoes for one month

Category

Treatment - Devices

2

Description

"Intervention group:" using lateral wedge in shoes with hip and trunk strengthening exercises for one month . exercises should be done 3 times in a day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation Science School of Shahid Beheshti Medical science

Full name of responsible person
Nafiseh Shahri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nafiseh Shahri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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