

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Acute and chronic effects of lateral wedge insoles with different inclination on biomechanical variables associated with osteoarthritis of the knee in individuals with genu varum

Protocol summary

Study aim

1. The study on the immediate and long term effect of lateral wedge insoles with different inclination on Knee adduction torque in individual having genu varum with similar foot structure in support phase of running.

Design

By completing the pretest, the subjects were randomly divided into experimental and control groups. The experimental group is divided into three subgroups. then we first assign a number to each participant and use the lottery to select the required number for each group. The experimental groups use an insole for eight weeks. After two months of, subjects in each group repeat the steps as post-tests.

Settings and conduct

The place of this study is Tehran. The test is recorded in five conditions: barefooted, with shoes, external inclination with gradients 0, 5, 10 for all subjects. They begin their movement from four meters of the board and by getting a controlled rhythm, the average of three successful attempts with the following characteristics is recorded. - impact of the foot with a ergometer board at the support stage of running. - The subject will naturally run and do not set his foot for a contact on board only.

Participants/Inclusion and exclusion criteria

Entry criteria: Having a 3rd grade parenthesis and age range of 20-35 years Exit criteria, having or history of: BMI greater than 30, lower limb joint rehabilitation program or fracture and surgery, osteoarthritis, ligament injury or knee minisc, use of foot and trunks in the six months before the measurement and systemic diseases

Intervention groups

Subjects were divided into four groups. The control group is without any intervention, but each of other three groups as an experimental group uses an external insoles that their inclination are different as 0, 5 and 10 degrees.

Main outcome variables

External insoles with different inclination percent
Biomechanical variables related to knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190414043273N1**

Registration date: **2019-06-13, 1398/03/23**

Registration timing: **retrospective**

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

mehdi GHEITASI

Name of organization / entity

The University of Shahid beheshti

Country

Iran (Islamic Republic of)

Phone

+98 21 2990 5839

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Acute and chronic effects of lateral wedge insoles with different inclination on biomechanical variables associated with osteoarthritis of the knee in individuals with genu varum

Public title
effects of lateral wedge insoles withon biomechanical variables associated with osteoarthritis of the knee

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
People with a Genu Varum
Exclusion criteria:
The history of the use of medical shoes and footwear in six months before the measurement Having a BMI of over 30

Age
From **25 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
In this method, we first assign all the participants in the numerical study and use the lottery to select the required number for each group.

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

Iran University of Medical Sciences

Street address

Tehran Hemat Highway next to Milad Tower 14496.

14535

City
Tehran

Province
Tehran

Postal code
14535 14496

Approval date
2019-02-23, 1397/12/04

Ethics committee reference number
IR.IUMS.REC.1397.1348

Health conditions studied

1

Description of health condition studied

Genu Varum

ICD-10 code

M21.1

ICD-10 code description

Varus deformity, not elsewhere classified

Primary outcomes

1

Description

Independent variable: insoles

Timepoint

eight weeks

Method of measurement

Hammer's General Health Questionnaire, Scale to measure anthropometric characteristics, foot scan to examine the type of plantar, ergometer machine, camera and marker to record motion and calculate the external knee attachment torque

2

Description

dependent variables: Genu Varum

Timepoint

eight weeks

Method of measurement

Hammer's General Health Questionnaire, Scale to measure anthropometric characteristics, foot scan to examine the type of plantar, ergometer machine, camera and marker to record motion and calculate the external knee attachment torque

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The intervention include use of semi-custom shoe insoles with an external gradient of 0 °

for eight weeks.

Category

Prevention

2

Description

Intervention group 2: Use of semi-custom shoe insoles with an external gradient of 5 ° for eight weeks.

Category

Prevention

3

Description

Intervention group 3: Use of semi-custom shoe insoles with an external gradient of 10 ° for eight weeks.

Category

Prevention

4

Description

Control group: They will not experience an intervention, and they will experience the use of their normal and insane shoes for eight weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Gholamreza Raeisi

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Tehran, Vali-e-Asr Square, Karim Khan Zand Avenue, Beh Afarin Street

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Gholamreza Raeisi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Ph.D.

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Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data will only be presented in general and in the results of the report of study.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

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