Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Biomechanical analysis of the gait of patients with knee osteoarthritis before and after the acute use of the lateral wedge sock insoles

Protocol summary

Study aim

The aim of this study is to analyze the biomechanical characteristics of gait in patients with knee osteoarthritis before and after the immediate use of lateral wedge sock insoles.

Design

It involves a control group and parallel groups, both of which are double-blind and randomized. The trial will be conducted on 60 patients without any phases. Block randomization, using a limited randomization approach, will be employed for the purpose of randomization.

Settings and conduct

BuAli Sina University

Participants/Inclusion and exclusion criteria

The study will include patients between the ages of 40 and 65 who have radiographic evidence of mild to moderate knee osteoarthritis, chronic knee pain lasting for one month or more, morning stiffness of less than 30 minutes, and crepitus. Patients with lower limb pain or lesions (excluding knee osteoarthritis), those who use stimulants, drugs, or alcohol, those with a history of neurological or muscular diseases or systemic illnesses such as rheumatism, diabetes, cardiovascular, or pulmonary diseases, those who have undergone surgery on the affected knee or received intra-articular PRP injection in the past six months, those who have a history of fractures or dislocations in the lower limb within the past year, and those who have engaged in a regular exercise program in the past six months will be excluded from the study. Additionally, patients with pain lasting less than one day per month and those who cannot walk without assistance will also be excluded.

Intervention groups

The intervention group will consist of participants who receive a specially designed sock lateral wedge insole. The control group will also comprise 30 participants who are similar to the experimental group in terms of age and gender and will receive a neutral insole with a zero-degree inclination.

Main outcome variables

Osteoarthritis symptoms, EKAM, Cop, Coordination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041914N2**
Registration date: **2023-04-30, 1402/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-30, 1402/02/10**
Update count: **0**

Registration date

2023-04-30, 1402/02/10

Registrant information

Name

Fereshteh Sabet

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7265

Email address

fereshteh_sabet@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Biomechanical analysis of the gait of patients with knee osteoarthritis before and after the acute use of the lateral wedge sock insoles

Public title
The effect of lateral wedge sock insoles on the gait of patients with knee arthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
age range of 40 to 65 years having radiological signs of mild to moderate osteoarthritis in the knee chronic knee pain for 1 month or more morning stiffness for less than 30 minutes Crepitus

Exclusion criteria:
The presence of any pain or lesion in the lower limb (except knee osteoarthritis) Use of stimulants, drugs and alcohol History of neurological and muscle diseases The presence of any systemic disease such as rheumatism Diabetes or a history of cardiovascular and pulmonary diseases History of any surgery in the affected knee Intra-articular injection (PRP) within the last six months History of fractures and dislocations in the lower limb during the past year Having a regular exercise program in the last six months Having pain less than one day per month Inability to walk without assistance

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the restricted randomization method of block randomization to balance the number of samples assigned to each group. Specifically, we will form 6 blocks of equal size, each containing 3 participants (3 in the intervention group and 3 in the control group). To generate the random sequence, we will use a software called Random Allocation Software, which can perform both simple randomization and blocking. We will also use concealment allocation to ensure that the assigned group of each participant remains unknown until the moment of assignment. To achieve this, we will use opaque sealed envelopes containing a sequentially numbered random sequence generated on a registration card. The cards themselves will be placed in letter envelopes in order. In order to maintain the randomized sequence, the outer surface of the envelopes will be numbered in the same order. Finally, we will glue the lid of each envelope and place them in a box. When we begin registering participants, we will open an envelope based on the order of entry of eligible participants into the study, revealing the assigned group for that participant.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, 60 patients will participate, who will be randomly divided into two control and experimental groups (according to the explanation in the previous section). The intervention group will receive a 6-degree lateral wedge sock insole and the control group will receive a 0-degree neutral insole as a placebo. The insoles will be provided to the participants by the clinical supervisor. Neither the participants nor the researchers and the members of the analysis and evaluation team will know which group received the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of BU-Ali Sina University, Hamedan

Street address
Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street

City
Hamedan

Province
Hamadan

Postal code
6516738695

Approval date
2022-09-06, 1401/06/15

Ethics committee reference number
IR.BASU.REC.1402.024

Health conditions studied

1

Description of health condition studied
Medial Compartment Knee Osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee OA Symptoms
Timepoint
Before and after the immediate use of the lateral wedge sock insoles
Method of measurement
WOMAC Questionnaire

Secondary outcomes

1

Description
Knee External Adduction Moment (EKAM)
Timepoint
Before and after the immediate use of the lateral wedge sock insoles
Method of measurement
Through kinematic data obtained from motion analysis system and kinetic data obtained from the force plate

2

Description
Coordination and variability of the coordinated pattern of hindfoot and the leg
Timepoint
Before and after the immediate use of the lateral wedge sock insoles
Method of measurement
Through kinematic data obtained from motion analysis System

3

Description
Center of Pressure (CoP) Path
Timepoint
Before and after the immediate use of the lateral wedge sock insoles
Method of measurement
Using the data obtained from the foot scanner (Foot pressure)

Intervention groups

1

Description
Intervention group: Using the lateral wedge sock insoles; The insole used in this study is designed as a sock for easy use at home without the need for shoes or sandals. As previous research has shown that the 6-degree insole is most effective in reducing pain and improving performance in patients, A 6-degree lateral wedge was selected. The stiffness of the sole will vary from hard on the lateral edge to softer on the medial side. The lateral part will be made of Plastazote foam with a hardness of A: 70, while the medial part will be made of Ethylene-vinyl acetate (EVA) with a hardness of A: 20. The insole supports both the internal longitudinal arch and the transverse arch of the foot to maximize patient comfort. Additionally, a subtalar strap will be used to prevent eversion behind the heel. The upper part of the insole will be made of soft material to ensure patient comfort. The affected foot will use a 6-degree lateral wedge insole, while a 0-degree neutral insole will be used for healthy feet to prevent leg length discrepancy.
Category
Rehabilitation

2

Description
Control group: For the control group, a zero-degree neutral insole will be used as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tawana physiotherapy and rehabilitation center
Full name of responsible person
Mr. Sufizadeh
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QGQ6+2PM, Hamedan, Hamadan Province
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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
Bu-Ali Sina University of Hamedan
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
Bu-Ali Sina university
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Position
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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
This file is confidential.
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
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
No - There is not a plan to make this available
Data Dictionary

No - There is not a plan to make this available