Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of orthoses by applying direct biomechanical force in comparison with orthoses applying indirect biomechanical effect on knee pain, function, satisfaction, and knee joint alignment in individuals with medial compartment knee osteoarthritis.

Protocol summary

Study aim

The aim of this study is to investigate and compare the performance of these three orthoses on pain, function, satisfaction and alignment of the knee in people with medial compartment of the knee osteoarthritis.

Design

A clinical trial study, single-blind, with three parallel groups, randomized, with 30 participants.

Settings and conduct

The first phase of the study includes designing a foot-ankle orthosis. Gait analysis is checked before and after in the laboratory. In the second phase, the desired variables before and after 6 weeks of using the orthosis will be compared by the KOOS(Knee injury and osteoarthritis outcome score questionnaire) and the AMI (Angle measurement using images of bony promineces) method. Only the code of each patient will be recorded on the patient files and all the questionnaires. Only the patient and the therapist will have access to the code. In this way, patient information will be protected.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 30 and 65 years. Having grade 2 or 3 medial knee osteoarthritis according to the Kellgren-Lawrence scale Not having movement restrictions. Being able to walk without walking aids. ; Exclusion Criteria: Having Varicose veins and other diseases that affect the gait. Having a history of recent knee injuries. Suffering from Neurological diseases diagnosed by a doctor. Having Ligamentous problems in the knee or torn meniscus. Inability to wear shoes (less than eight hours a day).

Intervention groups

There are three test groups. In each of the test groups, lateral wedge insole, Valgus knee braces, and "ankle foot orthoses" are randomly given.

Main outcome variables

Pain, Function, Satisfaction and Alignment of the Knee

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221017056212N1**
Registration date: **2023-05-20, 1402/02/30**
Registration timing: **retrospective**

Last update: **2023-05-20, 1402/02/30**
Update count: **0**

Registration date

2023-05-20, 1402/02/30

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

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of orthoses by applying direct biomechanical force in comparison with orthoses applying indirect biomechanical effect on knee pain, function, satisfaction, and knee joint alignment in individuals with medial compartment knee osteoarthritis.

Public title
Evaluation of the effect of orthoses in subjects with medial compartment knee osteoarthrtis.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30 and 65 years. According to radiological findings, the medial compartment of the knee should be in grade 2 or 3 based on the Kellgren- Lawrence scale. Patients should not have movement restrictions in walking and standing. Patients can walk without any help.
Exclusion criteria:
Varicose veins and other diseases that affect the gait. History of recent knee injuries Neurological diseases diagnosed by a doctor. Ligamentous problems in the knee - torn meniscus. Inability to wear shoes (less than eight hours a day).
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
University of Social welfare and Rehabilitation
Street address
Kodakyar Ave, Danshjo Blvd, Evin.
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Tehran
Province
Tehran
Postal code
1985713871
Approval date
2021-10-27, 1400/08/05
Ethics committee reference number
IR.USWR.REC.1400.166

Health conditions studied

1

Description of health condition studied
Medial Knee Osteoarthritis
ICD-10 code
M17.0
ICD-10 code description
Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description
Pain/ Alignment/ Function
Timepoint
Before intervention/ After 6 weeks
Method of measurement
Angle measurement using images of bony promineces for alignment of knee/Knee injury and osteoarthritis outcome score

Secondary outcomes

empty

Intervention groups

1

Description
1 Intervention group : Unloader brace It is used in patients with osteoarthritis of the internal compartment of the knee. The knee brace reduces the load from the internal compartment by creating a force of three pressure points by stretching the strap. The force of three pressure points reduces the pressure from the inner side of the knee by reducing the length of the lever arm, the force of the ground reaction and the subsequent reduction of the internal torque on the knee joint. The valgus knee brace used in this study has an internal load, crossed straps (applying external force), two loops, one in the thigh area and the other in the leg area, made of polypropylene, which are connected through a dynamic joint. Be Two-thirds of the femur at

the top and the tibia at the bottom are covered by the orthosis. To make a knee brace in three sizes, we have a circumference from the peak of the cuff muscles, the circumference of the knee joint and 17 cm above the knee. The knee orthosis will be made individually and custom made for each patient based on three sizes.

Category

Treatment - Devices

2

Description

2 Intervention group : Lateral wedge insole, Pre-made insoles will be given to patients based on their foot size. According to the studies, the insole covers the entire length of the sole of the foot, has arch support and 6 mm external wedge. In this study, a prefabricated insole with a 6-degree outer wedge made of cork material similar to thermocork with a density of 60 per meter will be used, which will be placed in the patient's comfortable walking shoes.

Category

Treatment - Devices

3

Description

3 Intervention group : Ankle foot orthosis, It is custom-made for each person, and in order to create valgus torque, an external wedge will be installed under the surface of the foot. Molding is done from each person's foot. Then, the mold is ready to be drawn after making the necessary corrections. The sheet used in this orthosis is made of polyethylene and is drawn on a mold made of each person's foot. The foot-ankle orthosis prevents the external rotation of the tibia by keeping the ankle joint and the tibia vertical, and we expect that by preventing the external rotation of the tibia, the lever arm of the ground reaction force will decrease as a result of the adductor torque on the knee joint.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
University of Social welfare and Rehabilitation

Full name of responsible person
Maede Mahmoodi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Aging Research Center

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
Maede Mahmoodi

Position
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Orthotics and Prosthetic

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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