

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of new ankle foot orthosis for patients with medial compartment osteoarthritis of the knee and Pilot study for evaluation of it's effect on joint contact force, gait parameters, function, usability, pain and quality of life

Protocol summary

Study aim

Evaluation of a new foot-ankle orthosis for patients with internal compartment osteoarthritis (OA) of the knee and a preliminary study of its effect on intra-articular force, gait parameters, performance, applicability, pain and quality of life of patients

Design

After the construction of the orthosis, the second phase of the pilot study in the form of a semi-experimental before and after study, the impact of the orthosis on clinical parameters (pain, symptoms, daily life activities, quality of life, satisfaction with the orthosis, comfort, fear of falling) and biomechanical will be investigated on ten patients with knee osteoarthritis

Settings and conduct

In order to perform the relevant tests, the patients are asked to walk along a certain path in the laboratory. Before the test, the patients get familiar with the laboratory environment and how to perform the test is explained to them. The place of the study is the Technical Orthopedics Department of the Faculty of Rehabilitation in Isfahan University of Medical Sciences and the study population is 10 patients with knee arthritis. No blinding will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 50 years old; The severity of knee osteoarthritis be mild to moderate (grade 2 or 3) based on radiographic findings and the Kellgren-Lawrence scale; Mild to moderate pain intensity (based on VAS scale, mild pain = 0-3, moderate pain = 4-6); Mild varus alignment in the knee with symptoms of osteoarthritis of the internal compartment of the knee. Exclusion criteria: History of knee joint replacement surgery; External compartment osteoarthritis (grade 1 and above); Having any cognitive or neurological disorder (Parkinson's, MS, etc.); The patient is

undergoing physiotherapy treatment or using other orthotic treatment.

Intervention groups

The research intervention includes a foot orthosis that covers the foot, ankle and part of the leg.

Main outcome variables

Pain; quality of life; inter-articular force

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047459N7**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

Masoud Rafiaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5043

Email address

ma.rafiaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of new ankle foot orthosis for patients with medial compartment osteoarthritis of the knee and Pilot study for evaluation of it's effect on joint contact force, gait parameters, function, usability, pain and quality of life

Public title

Evaluation of AFO on knee OA

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 50 years The severity of knee osteoarthritis be mild to moderate (grade 2 or 3) based on radiographic findings and the Kellgren-Lawrence scale Mild to moderate pain intensity (based on VAS scale, mild pain = 0-3, moderate pain = 4-6) Mild varus alignment in the knee with symptoms of osteoarthritis of the internal compartment of the knee Reporting of knee pain in most weekdays at least in the last month Not having movement restrictions in walking and standing Walking without any aids

Exclusion criteria:

History of knee replacement surgery History of lower limb fracture or knee ligament damage in the last year External compartment osteoarthritis (grade 1 and above) Having any cognitive or neurological disorder The patient is undergoing physiotherapy treatment or using other orthotic treatment

AgeFrom **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **10****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**

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-11-26, 1401/09/05

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.111

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M15.9

ICD-10 code description

Polyosteoarthritis, unspecified

Primary outcomes**1****Description**

Force inside the knee joint

Timepoint

Before and six weeks later

Method of measurement

force plate

2**Description**

pain

Timepoint

Before and six weeks later

Method of measurement

Before and six weeks later

3**Description**

quality of life

Timepoint

Before and six weeks later

Method of measurement
Before and six weeks later

Secondary outcomes

empty

Intervention groups

1

Description

This pilot study will be conducted on ten patients with internal compartment osteoarthritis. Sampling will be done by easy non-random method and the subjects will be selected from the patients referred to the orthopedic clinic who meet the conditions to enter the study. Informed and voluntary consent form will be obtained. The diagnosis of osteoarthritis of the knee will be confirmed by a specialist doctor, and information about the patient will be extracted using paraclinical measures, radiography and CT scan. The severity of osteoarthritis of patients will be determined by a specialist based on the Kellgren-Lawrence scale. In order to perform tests related to the measurement of time-spatial variables of walking, range of motion of joints, torques and contact forces of inter-articular surfaces, patients are asked to walk along a certain path in the laboratory and their information will be recorded by cameras. The orthosis covers the area of the sole of the foot up to the lower two-thirds of the leg, and by applying force in this area, it will have an indirect effect on the knee. After evaluating the patient and designing the orthosis and the place of application of force, the orthosis is made. The patient will be taught how to wear the orthosis and wear it for at least 4 hours a day during these 6 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences

Full name of responsible person

Masoud Rafiaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Rafiaei

Position

member of faculty

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available