

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Design and manufacturing of new “ankle foot orthosis for knee osteoarthritis” and evaluation of its effect on knee adduction moment and gait kinetic parameters in people with knee osteoarthritis.

Protocol summary

Study aim

Design and manufacturing of new “AFO” and evaluation of its effect on knee adduction moment and kinetic parameters of gait in people with knee OA

Design

Study design: Before- after design clinical trial. Sample size: 28 subjects with medial compartment knee OA
Study phases: Before wearing the orthosis and when wearing the orthosis

Settings and conduct

The current study will be carried out in faculty of rehabilitation science of Iran university of medical sciences and on the hospital outpatients who had prescribed by an orthopedic physician to use a knee orthosis.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Medial compartment knee OA with grade 2 or 3 of KL scale Age range 35- 70 years old BMI range 18.5 - 35 Exclusion Criteria Lateral compartment knee OA Rheumatoid Arthritis Osteoarthritis of ankle or hip or vertebral column or patellofemoral joint Chronic or severe disturbances that lead to change in the gait pattern of the participants and can be recognized by the researchers observational assessment. History of operation in lower limb History of injection or operation in the last 6 months

Intervention groups

Intervention group: people with knee osteoarthritis after wearing "AFO for Knee OA" orthosis. Control group: people with knee osteoarthritis before wearing "AFO for Knee OA" orthosis.

Main outcome variables

Comport- Knee adduction moment- Kinetic parameters when walking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160904029684N3**

Registration date: **2019-03-19, 1397/12/28**

Registration timing: **prospective**

Last update: **2019-03-19, 1397/12/28**

Update count: **0**

Registration date

2019-03-19, 1397/12/28

Registrant information

Name

Kourosh Barati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 935 882 7110

Email address

barati.k@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-03, 1398/01/14

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and manufacturing of new "ankle foot orthosis for knee osteoarthritis" and evaluation of its effect on knee adduction moment and gait kinetic parameters in people with knee osteoarthritis.

Public title

Design and manufacturing of "new orthosis for knee osteoarthritis" and evaluation of its effect on gait in people with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Medial compartment knee OA with grade 2 or 3 of KL scale Age range 35- 70 years old BMI range 18.5 - 35

Exclusion criteria:

Lateral compartment knee OA Rheumatoid Arthritis Osteoarthritis of ankle or hip or vertebral column or patellofemoral joint Chronic or severe disturbances that lead to change in the gait pattern of the participants and can be recognized by the researchers observational assessment. History of operation in lower limb History of injection or operation in the last 6 months

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

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 Iran University of Medical Science

Street address

Shahnazari st.- Mirdamad Blvd.- Tehran

City

tehran

Province

Tehran

Postal code

۱۳۴۸۷ - ۱۵۴۵۹

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.IUMS.REC.1397.1120

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.10

ICD-10 code description

Unilateral primary osteoarthritis, unspecified knee

Primary outcomes

1

Description

Knee adduction moment

Timepoint

Before wearing orthosis and after wearing orthosis

Method of measurement

Force plate synchronized with the motion analysis instrument

2

Description

Comfort

Timepoint

Before wearing orthosis and after wearing orthosis

Method of measurement

questionnaire

3

Description

Kinetic parameters

Timepoint

Before wearing orthosis and after wearing orthosis

Method of measurement

Force Plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants with knee OA will

perform the biomechanical test in three conditions: when wearing no orthosis, when wearing "AFO for Knee OA" Orthosis with un-lucked supination/pronation joint and when wearing "AFO for Knee OA" Orthosis with lucked supination/pronation joint.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firouzgar Hospital

Full name of responsible person

Kourosh Barati

Street address

Firouzgar Hospital, Firouzeh St., Valiasr St., Valiasr Sq.,

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Kouhpayeh

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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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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

Koorosh Barati

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Prostheses & Orthoses

Street address

Department of Orthosis & prosthesis, School of rehabilitation Sciences, Shahnazari St, Madar Sq, Mirdamad Ave, Tehran, Iran

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Koorosh Barati

Position

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Latest degree

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Other areas of specialty/work

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Fax**Email**

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Web page address**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After ensuring that the participants are not identifiable, all potential data could be shared

When the data will become available and for how long

6 month after article publication

To whom data/document is available

Researchers that are working in IUMS

Under which criteria data/document could be used

In condition in which the priority of research innovation is not threatened

From where data/document is obtainable

Sending the request to the corresponding author via email.

What processes are involved for a request to access data/document

The request is reviewed by the corresponding author and the decision will be made within 2 weeks of after receiving the request.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Koorosh Barati

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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