Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Design

Study design: Before- after design clinical trial. Ṡample 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 addaction 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)

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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 addaction 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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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

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Person responsible for updating data

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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