Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the immediate effect of distractive “KIA-knee” knee brace on reduction of adduction moment and pain in patients with knee osteoarthritis

Protocol summary

Study aim

Investigating the immediate effect of “KIA-knee” knee brace on knee adduction and flexion moment, knee angle in the frontal plane, ground reaction force and pain in patients with knee osteoarthritis

Design

The study is clinical trial without a control group. The sample size is 16 people and sampling is done by random method. In this research, only one group is studied, and our intervention is distractive “KIA-knee” knee brace.

Settings and conduct

This research is carried out in the Skeletal-Muscular Research Center, Isfahan University of Medical Sciences.16 people with knee osteoarthritis are evaluated and the evaluations include gait test and pain questionnaire in two situations with knee brace and without knee brace.

Participants/Inclusion and exclusion criteria

Conditions for entering: suffering from osteoarthritis of the medial compartment of the knee, mild or moderate severity, age range of 40 to 70 years, the level of pain (VAS index) equal to or greater than 4, the severity of knee varus deformity in the anterior-posterior view is 2 to 11 degrees, BMI is equal to or less than 35, no injection of hyaluronic acid or corticosteroids in the last 6 months, no use of other orthoses; Exit conditions: indication for knee joint surgery, suffering from simultaneous osteoarthritis of the hip or ankle joints or feet on the same or opposite side, heart or lung diseases, rheumatoid arthritis, skin disorders, infection, diabetes, Acute inflammation of the knee, deep vein thrombosis, a history of stroke and history of knee arthroplasty surgery

Intervention groups

In this study, 16 people with knee osteoarthritis receive a type of distractive knee brace that called “KIA-knee” knee brace and this study does not include the control group.

Main outcome variables

Pain score, knee adduction and flexion moment, knee angle in the frontal plane and ground reaction force

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220824055786N1**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**
Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Maryam Abbasi dashtaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3338 7950

Email address

maryam.abasi.d76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-31, 1401/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the immediate effect of distractive “KIA-knee” knee brace on reduction of adduction moment and pain in patients with knee osteoarthritis

Public title

Evaluation of the immediate effect of distractive “KIA-knee” knee brace on reduction of adduction moment and pain in patients with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having medial knee osteoarthritis The severity of osteoarthritis is mild or moderate (Kelgren-Lawrence classification) based on the graph prepared in the last 6 months Has an age range of 40 to 70 years The amount of pain at rest (VAS index) is equal to or more than 4 Severity of knee varus deformity based on graph in anterior-posterior view is 2 to 11 degrees BMI is equal to or less than 35 No injections of hyaluronic acid or corticosteroids in the last 6 months No use of other orthoses

Exclusion criteria:

Indications for knee joint surgery according to the opinion of an orthopedic specialist Suffering from concurrent arthritis of hip or ankle joints or feet on the same or opposite side Having heart or lung diseases, rheumatoid arthritis, skin disorders, infection, diabetes, acute knee inflammation, knee pain caused by other factors or deep vein thrombosis History of stroke History of fracture around the knee or total or partial knee arthroplasty surgery

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Faculty of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.062

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee adduction moment

Timepoint

Measurement of the knee adducton moment in gait before and after using distractive “KIA-knee” knee brace.The immediate effect is investigated.

Method of measurement

Visual 3D motion analysis software

2

Description

Knee flexion moment

Timepoint

Measurement of the knee flexion moment in gait before and after using distractive “KIA-knee” knee brace.The immediate effect is investigated.

Method of measurement

Visual 3D motion analysis software

3

Description
Ground reaction force
Timepoint
Measurement of the ground reaction force during gait before and after using distractive “KIA-knee” knee brace.The immediate effect is investigated.
Method of measurement
Force plate

4

Description
Knee angle in the frontal plane
Timepoint
Measurement of the knee angle in the frontal plane during gait before and after using distractive “KIA-knee” knee brace.The immediate effect is investigated.
Method of measurement
Visual 3D motion analysis software

5

Description
Pain
Timepoint
Measuring the amount of pain before and after using distractive “KIA-knee” knee brace based on Visual Analogue Scale
Method of measurement
The pain questionnaire, which includes a 10 cm line, and the person participating in the study shows his pain level as a vertical line on this scale before and after using the knee brace.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, for 16 patients with knee osteoarthritis, distractive “KIA-knee” knee brace will be designed and manufactured in the appropriate size for each patient. This knee brace is a redesigned example of OA Knee Trac Brace and by the triangular leverage traction system used in the joint of the knee brace, the weight is removed from both compartments when the knee position is changed from flexion to extension. Evaluations are done in 2 stages with knee brace and without knee brace.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Dr. Hamid Mousavi
Street address
Orthopedic clinic, Al-Zahra specialized hospital, Shohday sofe Blvd., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
maryam.abasi.d76@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
Street address
Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3060
Email
askari@mui.ac.ir
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
Dr. Hossein Asiyaeimehr
Position
Assistant professor and faculty member of Orthotics and Prosthetics department
Latest degree
Ph.D.
Other areas of specialty/work
Orthotics and Prosthetics
Street address
Faculty of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5081
Fax
+98 31 3668 7270
Email
asiyaeimehr@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Hossein Asiyaeimehr
Position
Assistant professor and faculty member of Orthotics and Prosthetics department
Latest degree
Ph.D.
Other areas of specialty/work
Orthotics and Prosthetics
Street address
Faculty of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5081
Fax
+98 31 3668 7270
Email
asiyaeimehr@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Hossein Asiyaeimehr
Position
Assistant professor and faculty member of Orthotics and Prosthetics department
Latest degree
Ph.D.
Other areas of specialty/work
Orthotics and Prosthetics
Street address
Faculty of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5081
Fax
+98 31 3668 7270
Email
asiyaeimehr@gmail.com

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Study information (other than individual information) will be shared with other researchers.
When the data will become available and for how long
Information will be shared after results or data summaries are published.
To whom data/document is available
Information will be shared for academic purposes only.
Under which criteria data/document could be used
Information is shared for the teaching and research of applicants.
From where data/document is obtainable
People can request information from the introduced responsible person.
What processes are involved for a request to access data/document
Requests must be sent via email (asiyaeimehr@gmail.com).
Comments