Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of brace adjustment with optimal dosage method and conventional method on clinical parameters

Protocol summary

Study aim
Comparison of the effect of brace adjustment with the optimal dosage method and the conventional method on clinical parameters

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized, on 30 patients.

Settings and conduct
In this study, a comparison of brace adjustment based on the optimal applied force (new method) and patient's comfort (conventional method) on clinical parameters will be performed. Participants will be blinded. Moreover, the study will be performed in the biomechanics laboratory of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Patients with medial compartment of knee osteoarthritis with grade 2 and 3 according to the Kelgren Lawrence classification will be include . lateral compartment of knee osteoarthritis or grade 1 and 4 osteoarthritis will excluded.

Intervention groups
Both intervention and control groups will receive knee braces. The knee brace will be adjusted based on the optimal dose for the study group and based on patient comfort for the control group.

Main outcome variables
Pain level(primary outcome), Function(secondary outcome), Satisfaction level(secondary outcome).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210709051829N1**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **registered_while_recruiting**
Last update: **2021-10-02, 1400/07/10**
Update count: **0**

Registration date
2021-10-02, 1400/07/10

Registrant information

Name
Mobina Khosravi farsani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7737 6127

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mobinakhosravi80@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-21, 1400/06/30

Expected recruitment end date
2022-02-04, 1400/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of brace adjustment with optimal dosage method and conventional method on clinical parameters

Public title
Determining the optimal pressure by the knee brace in knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with medial knee osteoarthritis Disease severity 2 and 3 based on Kelgren-Lawrence scale(Second degree: reduction of joint space, third degree: second degree symptoms with the appearance of osteophytes) Age range 65-50 years Body mass index less than 30
Exclusion criteria:
Heart and respiratory diseases that limit the ability of patients to walk or a history of stroke lateral compartment knee osteoarthritis Perform any surgery on any of the lower limb joints Having a history of ligament reconstruction surgery, hip and knee arthroplasty and tibial osteotomy Factors that lead to impaired orthosis use such as infection, neurological diseases, skin disorders Quadriceps muscle weakness (strength lower or equal 3 based on manual muscle test) Knee flexion contraction, ligament laxity

Age
From **50 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple random method will be used. In this way, 30 cards numbered from 1 to 30 will be placed into a bowl. Then one card will be randomly taken out of the bowl each time. Thus, 15 cards will be selected and the number registered in them will be considered as study group. The remaining numbers in the bowl will be considered as a control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants in this study were not aware of the differences in knee joint pressure regulation between the control and intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Shahid Hemmat Highway, Tehran,IRAN.

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-08-08, 1400/05/17

Ethics committee reference number
IR.IUMS.REC.1400.414

Health conditions studied

1

Description of health condition studied
Medial knee compartment osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain level in patiants with medial knee osteoarthritis

Timepoint
Before the intervention and six weeks after the intervention

Method of measurement
Visual analoge scale

Secondary outcomes

1

Description
Function level in patiants with medial knee osteoarthritis.

Timepoint
Before and 6 weeks after intervention.

Method of measurement
The Western Ontario and McMaster Universities Arthritis Index questionnaire

2

Description
Satisfaction level in patiants with medial knee osteoarthritis.

Timepoint
Before and 6 weeks after intervention.

Method of measurement
Orthotics Prosthetics Users Survey.

Intervention groups

1

Description
Intervention group: Adjusted knee brace based on the optimal dose evaluated in the present study
Category
Rehabilitation

2

Description
Control group: Knee braces adjusted according to the conventional method (by the individual)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Sezar Ghobad's private clinic
Full name of responsible person
Mobina Khosravi
Street address
Shohada Square, Mojahedin Islam Street, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research Of Iran University of Medical Science
Full name of responsible person
Dr SeyyedAbbas Motevalian
Street address
Tehran Hemat Highway next to Milad Tower، 14535
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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
Vice Chancellor For Research Of Iran University of Medical Science
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
Mobina khosravi
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work
Orthopedics
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Title and more details about the data/document

Individuals information will remain confidential, but information about the variables studied in the present study can be shared.

When the data will become available and for how long

Up to two years after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In order to use the information for use in meta-analysis studies.

From where data/document is obtainable

Mobina khosravi mobina khosravi80@yahoo.com

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

Up to two years after the publication of the results, the applicant can send an email to the mentioned e-mail address and state the reason for the need for information. If the reason is reasonable, information will be sent to him as soon as possible.

Comments