

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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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Email address

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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.

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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 patients with medial knee osteoarthritis

Timepoint

Before the intervention and six weeks after the intervention

Method of measurement

Visual analogue scale

Secondary outcomes**1****Description**

Function level in patients 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 patients 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

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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

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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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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