

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the efficacy of an unloading knee brace equipped with vibration stimulation Vs conventional unloading knee brace on functional performance, external knee adduction moment and activation level of lateral side of the surrounding knee muscles, in subjects with knee osteoarthritis.

Protocol summary

Study aim

Comparison of the efficacy of an unloading knee brace equipped with vibration stimulation Vs conventional unloading knee brace on functional performance, external knee adduction moment and activation level of lateral side of the surrounding knee muscles, in subjects with knee osteoarthritis.

Design

The proposed study is a clinical trial and is designed to be conducted as a Randomized Control Trial (RCT). Participants will be randomly allocated to the experimental and control groups. Baseline assessments will be performed for all the participants. Those with experimental group will be supplied with the vibratory knee orthosis and those with control group will be supplied by the conventional knee OA brace. Finally, after 6 weeks, all the participants will be re-assessed.

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

The participants in intervention group will use the unloader knee brace equipped with vibrator for 6 weeks. The participants in control group will use the custom unloader knee brace for 6 weeks.

Main outcome variables

Functional performance; Knee adduction moment; Muscular activation level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160904029684N2**
Registration date: **2018-10-24, 1397/08/02**
Registration timing: **prospective**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

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

2018-12-22, 1397/10/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of an unloading knee brace equipped with vibration stimulation Vs conventional unloading knee brace on functional performance, external knee adduction moment and activation level of lateral side of the surrounding knee muscles, in subjects with knee osteoarthritis.

Public title

Comparison of the efficacy of an unloading knee brace equipped with vibration stimulation Vs conventional unloading knee brace in subjects 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

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants of the current study will be randomly assigned in two groups of intervention and control, using simple random method.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Faculty of Rehabilitation Sciences of Iran University of Medical Sciences, Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

۱۳۴۸۷ - ۱۵۴۵۹

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IUMS.REC.1397.302

2

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Faculty of Rehabilitation Sciences of Iran University of Medical Sciences, Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran

City

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Postal code

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Approval date

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Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Functional performance

Timepoint

before receiving the intervention and 6 weeks after receiving the intervention

Method of measurement

KOOS questionnaire

2

Description

Knee adduction moment

Timepoint

before receiving the intervention and 6 weeks after receiving the intervention

Method of measurement

Force plate synchronized with the motion analysis instrument

3

Description

Activation Level

Timepoint

before receiving the intervention and 6 weeks after receiving the

Method of measurement

Using electrocardiography instrument

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants in intervention group will use the unloader knee brace equipped with vibrator for 6 weeks.

Category

Rehabilitation

2

Description

Control group: The participants in control group will use the custom unloader knee brace for 6 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Ismail Ebrahimi Takamjani

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran National Science Foundation

Full name of responsible person

Nosrat-allah Zargham

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5th St., Kargar Sholami St.

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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 National Science Foundation

Proportion provided by this source

25

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ismail Ebrahimi Takamjani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Kourosh Barati

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Orthotics & Prosthetics

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

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Ismail Ebrahimi Takamjani

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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

Iran University of Medical Sciences

Full name of responsible person**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