Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 activitition 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

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Iran University of Medical Sciences

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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 activitition 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
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Postal code
۱۳۴۸۷ - ۱۵۴۵۹

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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Sponsors / Funding sources

1

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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
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Ismail Ebrahimi Takamjani
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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