Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Designing, manufacturing and evaluating the effectiveness of prayer knee brace in patients with mild knee osteoarthritis pain

Protocol summary

Study aim

Designing and manufacturing of prayer knee brace in patients with mild knee osteoarthritis pain Evaluation of the effect of prayer knee brace on pain in patients with mild knee osteoarthritis pain Evaluation of the effect of prayer knee brace on Joint stiffness in patients with mild knee osteoarthritis pain Evaluation of the effect of prayer knee brace on functional activity in patients with mild knee osteoarthritis pain Evaluation of the effect of prayer knee brace on range of motion in patients with mild knee osteoarthritis pain

Design

Interventional study, without control group and blinding

Settings and conduct

The first stage is the design and manufacture of prayed knee brace. In the second stage, participants filled the WOMAC questionnaire and the range of knee joint was measured by goniometer. After 30 days use of knee brace the evaluation repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Knee osteoarthritis Grade 3 and 4 (Kellgren-lawrence Grade) According to the orthopedic surgeon Age between 30 - 60 years Mild knee pain based on Visual Analog Scale History of surgery associated with the disease (such as replacement and joint repair) Exclusion criteria: History of knee fracture Chronic illness such as insulin-dependent diabetes or lupus Corticosteroid injections into the knee joint during the 30 days prior to the intervention or the injection program until the end of the study period

Intervention groups

prayer knee brace are designed and manufactured for participant with knee pain due to knee osteoarthritis. This knee brace is light and does not prevent knee bending. The area of the petal is soft, and when kneeling, it prevents loading on the knee.

Main outcome variables

pain, joint stiffness, functional activity, range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040148N2**
Registration date: **2019-05-01, 1398/02/11**
Registration timing: **prospective**

Last update: **2019-05-01, 1398/02/11**
Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name

Masumeh Bagherzadeh Cham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1612

Email address

bagherzadehcham.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, manufacturing and evaluating the effectiveness of prayer knee brace in patients with mild knee osteoarthritis pain

Public title
prayer knee brace
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Knee osteoarthritis Grade 3 and 4 (Kellgren-lawrence Grade) According to the orthopedic surgeon Age between 30 - 60 years Mild knee pain based on Visual Analog Scale
Exclusion criteria:
History of surgery associated with the disease (such as replacement and joint repair) History of knee fracture Chronic illness such as insulin-dependent diabetes or lupus Corticosteroid injections into the knee joint during the 30 days prior to the intervention or the injection program until the end of the study period
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **10**
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 Iran University of Medical Sciences
Street address
Hemat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-07-29, 1397/05/07
Ethics committee reference number
IR.IUMS.REC.1397.419

Health conditions studied

1

Description of health condition studied
patients with mild knee osteoarthritis pain
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain rate when kneeling based on WOMAC questionnaire
Timepoint
Before intervention and 30 days after knee brace use
Method of measurement
WOMAC questionnaire (Western Ontario and McMaster osteoarthritis index)

2

Description
Joint stiffness
Timepoint
Before intervention and 30 days after knee brace use
Method of measurement
WOMAC questionnaire (Western Ontario and McMaster osteoarthritis index)

3

Description
Functional activity
Timepoint
Before intervention and 30 days after knee brace use
Method of measurement
WOMAC questionnaire (Western Ontario and McMaster osteoarthritis index)

4

Description
Range of motion
Timepoint
Before intervention and 30 days after knee brace use
Method of measurement
Digital goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: prayed knee brace. Light and thin knee brace that do not prevent knee bending. The anterior side of the knee brace is made of foam, which reduces knee forces when kneeling.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Firozgar hospital
Full name of responsible person
Masumeh Bagherzadeh Cham
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Valiasr Square, Karim Khan St., Beh Afarin St., Firoozgar Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Kazem Malakoti
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Hemat Highway next to Milad Tower, Iran University of Medical Sciences
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research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Masumeh Bagherzadeh Cham
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Rehabilitation management
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Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after unidentifiable people

When the data will become available and for how long

starting one year after article publication

To whom data/document is available

Information is available to all researchers working in academic and scientific institutions

Under which criteria data/document could be used

use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article.

From where data/document is obtainable

connect to Dr Masumeh Bagherzadeh Cham by email: masumehbagherzadeh@gmail.com

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

If information is used in scientific and therapeutic activities, information is provided as soon as possible.

Comments