

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

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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.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Seyed Kazem Malakoti

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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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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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