

# 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**

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

#### Street address

Valiasr Square, Karim Khan St., Beh Afarin St.,  
Firoozgar Hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

1593747811

#### Phone

+98 21 8214 1612

#### Email

masumehbagherzadeh@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Seyed Kazem Malakoti

#### Street address

Hemat Highway next to Milad Tower, Iran University  
of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۳۳۹۶۱۴۵۳۵

#### Phone

+98 21 86701

#### Email

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

#### Street address

Firozgar Hospital, Behafarin St, Valiasr St

#### City

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#### Phone

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#### Email

BagherzadehCham.m@iums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Masumeh Bagherzadeh Cham

#### Position

Assistant Professor

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

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Masumeh Bagherzadeh Cham

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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