

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Prevalence and causes of persistent pain in patients after total knee arthroplasty in one year follow-up

#### Protocol summary

##### Study aim

Prevalence and causes of persistent pain in patients after total knee arthroplasty in one year follow-up

##### Design

Clinical trial without control group, phase 3 on 300 patients

##### Settings and conduct

This study is performed in Kashani Hospital in Isfahan. Patients will undergo surgery, then patients' pain before and one month, three months and one year after the intervention will be measured by the Western Ontario and McMaster Osteoarthritis Index.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for knee replacement surgery (TKA), knee pain due to severe osteoarthritis with and without severe deformity, severe pain due to chondrocalcinosis and pseudogout, severe patellofemoral arthritis in the elderly, consent to participate in this study. Exclusion criteria: active or recent infection of the knee, active infection in another specific part of the body, extensor mechanism mechanism, recurvatum due to muscular problem, functional and painless arthrodesis

##### Intervention groups

Intervention group: Patients in this group undergo total knee arthroplasty surgery. Patients' pain before and one month, three months and one year after the intervention is measured by the Western Ontario and McMaster Osteoarthritis Index.

##### Main outcome variables

Intensity of pain.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200217046523N7**

Registration date: **2020-12-22, 1399/10/02**

Registration timing: **prospective**

Last update: **2020-12-22, 1399/10/02**

Update count: **0**

##### Registration date

2020-12-22, 1399/10/02

##### Registrant information

###### Name

Aryan Rafiee Zadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3837 1582

###### Email address

rafieezadeh.a@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-24, 1399/10/04

##### Expected recruitment end date

2021-01-25, 1399/11/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prevalence and causes of persistent pain in patients after total knee arthroplasty in one year follow-up

##### Public title

Prevalence and causes of persistent pain in patients after total knee arthroplasty

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patient Candidate for Knee Replacement Surgery (TKA)  
Knee pain due to severe osteoarthritis with and without  
severe deformity Severe pain due to chondrocalcinosis  
and pseudogout Severe patellofemoral arthritis in the  
elderly Having informed consent of patients to  
participate in the study

**Exclusion criteria:**

Active or recent knee infection Active infection in another  
specific part of the body Extensor mechanism disorder  
Recurvatum due to muscular problem Functional and  
painless arthrodesis

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **300**

**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 Esfahan university of Medical  
sciences

**Street address**

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۸۱۳۷۸۶۶۵۱۵

**Approval date**

2020-11-25, 1399/09/05

**Ethics committee reference number**

IR.MUI.MED.REC.1399.755

**Health conditions studied**

1

**Description of health condition studied**

Osteoarthritis

**ICD-10 code**

M16

**ICD-10 code description**

Osteoarthritis of hip

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

Before and one month and three months and one year  
after the intervention

**Method of measurement**

Western Ontario and McMaster Osteoarthritis Index

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Patients in this group undergo total  
knee arthroplasty surgery. Patients' pain before and one  
month, three months and one year after the intervention  
is measured by the Western Ontario and McMaster  
Osteoarthritis Index.

**Category**

Treatment - Surgery

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Kashani Hospital

**Full name of responsible person**

Mehdi Motiffard

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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**Email**

motiffard@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

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Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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haghjoo.sh@med.mui.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehdi Motiffard

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for scientific inquiries

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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Esfahan University of Medical Sciences

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**Email**

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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**

All data can be shared after people have requested.

**When the data will become available and for how long**

Six months after publishing the results.

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Scientific uses

**From where data/document is obtainable**

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

**Comments**