

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673118

Phone

+98 31 3668 0048

Email

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3337 7986

Email

motiffard@med.mui.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Motiffard

Position

Associate professor

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+98 31 3337 7986

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Person responsible for updating data

Contact**Name of organization / entity**

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