Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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Province

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Postal code

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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 Motififard

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Sponsors / Funding sources

1

Sponsor
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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
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Associate professor
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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