

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of Clinical outcomes and complications of bilateral knee joint replacement simultaneously and after 48 hours

Protocol summary

Study aim

Comparison of clinical results and side effects of bilateral knee replacement simultaneously and 48 hours apart

Design

The study is a clinical trial using convenient non-probabilistic sampling method on 100 patients who are candidates for both knee joints. Patients will be divided into two groups of 50 people. For one group, both knee joints will be replaced at the same time, and for the other group, bilateral knee joints will be replaced 48 hours apart

Settings and conduct

This clinical trial study will be performed on people who were candidates for replacement of both knee joints and referred to Shahid Bahonar Hospital in Kerman in 1398.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients are candidates for joint replacement of both knees
Exclusion criteria: Previous major knee surgery; History of joint infection; Chronic diseases such as diabetes; Immunodeficiency; Infection of other parts of the body or recent active infection

Intervention groups

first group: Patients who will have bilateral knee joints replacement simultaneously
second group: Patients who will have bilateral knee joints replacement 48 hours apart

Main outcome variables

Infection (Purulent discharge from the surgical site and redness and warmth and tenderness of the surgical site)
: Deep vein thrombosis : Duration of hospitalization : Pain
: Swelling : joint Instability : joint Locking : Stair climbing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042514N6**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **retrospective**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

Halimeh Kameshki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3281 8065

Email address

halimeh.kameshki@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-11, 1398/05/20

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

2019-08-11, 1398/05/20

Actual recruitment end date

2020-02-04, 1398/11/15

Trial completion date

2020-05-09, 1399/02/20

Scientific title

Comparison of Clinical outcomes and complications of bilateral knee joint replacement simultaneously and after 48 hours

Public title

Comparison of Clinical outcomes and complications of bilateral knee joint replacement simultaneously and after

48 hours

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are candidates for joint replacement of both knees all patient were from ASAI,II class

Exclusion criteria:

Previous major knee surgery History of joint infection
Chronic diseases such as diabetes Immunodeficiency
Infection of other parts of the body or recent active infection

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ibn Sina avenue; Jahad Blvd

City

kerman

Province

Kerman

Postal code

76198131592

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.KMU.REC.1398.221

Health conditions studied

1

Description of health condition studied

knee joint

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Infection (Purulent discharge from the surgical site and redness and warmth and tenderness of the surgical site)

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Physical examination

2

Description

Deep vein thrombosis

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Physical examination - sonography

3

Description

Duration of hospitalization

Timepoint

After surgery

Method of measurement

Physical examination

4

Description

Stair climbing

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Lysholm questionnaire

5

Description

Joint Locking

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Lysholm questionnaire

6

Description

Joint Instability

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Lysholm questionnaire

7**Description**

Swelling

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Lysholm questionnaire

8**Description**

Pain

Timepoint

2 week -1 months - 3 months After surgery

Method of measurement

Lysholm questionnaire

Secondary outcomes

empty

Intervention groups1**Description**

Intervention group: first group includes patients who will have bilateral knee joints replacement Simultaneously : All patients will undergo the same anesthesia. Surgical method will be the same in all patients (classic knee replacement surgery) . antibiotics (48 hours of injectable cephalexin and then thirty cephalexin 500 mg every 6 hours) and painkillers (injection of one gram of apotel every eight hours). For 48 hours and then taking codeine acetaminophen every eight hours until five days after discharge) and anticoagulants (taking subcutaneous clexan for 14 days after discharge and all the time hospitalized once a day) will be the same after surgery too

Category

Treatment - Surgery

2**Description**

Intervention group: The second group includes patients who will have bilateral knee joints replacements 48 hours apart : All patients will undergo the same anesthesia. Surgical method will be the same in all patients (classic knee replacement surgery) . antibiotics (48 hours of injectable cephalexin and then thirty cephalexin 500 mg every 6 hours) and painkillers (injection of one gram of apotel every eight hours). For 48 hours and then taking codeine acetaminophen every eight hours until five days after discharge) and anticoagulants (taking subcutaneous clexan for 14 days after discharge and all the time hospitalized once a day) will be the same after surgery too

Category

Treatment - Surgery

Recruitment centers1**Recruitment center****Name of recruitment center**

Shahid Bahounar Hospital

Full name of responsible person

Dr Afshin Heshmati

Street address

Qarani Avenue

City

Kerman

Province

Kerman

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7613747181

Phone

+98 34 3223 5011

Email

amirreza.mirzaei@live.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Dr Afshin Heshmati

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Province

Kerman

Postal code

1355576169

Phone

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Email

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

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Amirreza Mirzaei Sosafidi

Position

Residency of Orthopedic

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No subscription required

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available