Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 groups

1

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 centers

1

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
Postal code
7613747181
Phone
+98 34 3223 5011
Email
amirreza.mirzaei@live.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr Afshin Heshmati
Street address
Haft Baghe Alavi
City
Kerman
Province
Kerman
Postal code
1355576169
Phone
+98 34 3325 7660
Email
amirreza.mirzaei@live.com
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
Street address
Qarani Avenue
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
amirreza.mirzaei@live.com

Person responsible for scientific 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
Street address
Qarani Avenue
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
amirreza.mirzaei@live.com
Web page address

Person responsible for updating data

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
Street address
Qarani Avenue
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
amirreza.mirzaei@live.com

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