Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the relationship between length of hospital stay with the outcome of the operation, quality of life and subsequent complications in patients undergoing knee and pelvic joint replacement surgery

Protocol summary

Study aim
Evaluation of the relationship between length of hospital stay with the outcome of the operation, quality of life and subsequent complications in patients undergoing knee and pelvic joint replacement surgery

Design
Clinical trial without control group with parallel, randomized, phase 3 groups on 60 patients A random number table was used for randomization.

Settings and conduct
This study is performed in Kashani Hospital in Isfahan. Patients are randomly divided into two groups. Patients are discharged within 24 hours and 72 hours. The quality of life and function of their joints are measured and compared with each other.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, first candidate for knee replacement surgery, candidate for first pelvic joint surgery, no cognitive impairment, consent to participate in the study. Exclusion criteria: Failure to follow up and examine the patient's condition within one year after knee replacement surgery, Failure to follow up and examine the patient's condition within one year after pelvic-hip replacement surgery, death of the patient, Having chronic diseases that require special care of the patient.

Intervention groups
Intervention group 1: Patients in this group undergo a 48-hour intervention and care approach. In this group, patients will be admitted 24 hours before and 24 hours after surgery. In this group, patients will be treated with a fast-track protocol of 48 hours. Intervention group 2: Patients in this group undergo 96-hour intervention and care approach. In this group, patients will be admitted 24 hours before and 72 hours after surgery. In this group, patients will be treated with routine ward protocols. The quality of life and joint function scores are measured before and after surgery at visits.

Main outcome variables
Quality of life and function of the patient's joints

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200217046523N13**
Registration date: **2021-03-25, 1400/01/05**
Registration timing: **prospective**

Last update: **2021-03-25, 1400/01/05**
Update count: **0**

Registration date
2021-03-25, 1400/01/05

Registrant information

Name
Aryan Rafiee Zadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 83 3837 1582
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rafieezadeh.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-08, 1400/01/19

Expected recruitment end date
2021-05-09, 1400/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the relationship between length of hospital stay with the outcome of the operation, quality of life and subsequent complications in patients undergoing knee and pelvic joint replacement surgery

Public title
Relationship between length of hospital stay and outcome, quality of life and complications
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years First-time candidate for knee replacement surgery Candidate for the first pelvic joint replacement surgery No cognitive impairment Satisfaction to participate in the study
Exclusion criteria:
Failure to follow up and examine the patient's condition within one year of knee replacement surgery Failure to follow up and examine the patient's condition within one year after pelvic-hip replacement surgery Death of the patient Having chronic diseases that require special care of the patient.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.
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 IsfahanUniversity of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-03-15, 1399/12/25
Ethics committee reference number
IR.MUI.MED.REC.1399.1180

Health conditions studied

1

Description of health condition studied
Arthritis of the joints
ICD-10 code
B42.82
ICD-10 code description
Sporotrichosis arthritis

Primary outcomes

1

Description
Quality of Life
Timepoint
Before surgery and 1, 3 and 6 months and one year after surgery
Method of measurement
Short Form Questionnaire -36

2

Description
Patient joint function
Timepoint
Before surgery and 1, 3 and 6 months and one year after surgery
Method of measurement
Knee Society score and Harris Hip Score questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group undergo a 48-hour intervention and care approach. In this group, patients will be admitted 24 hours before and 24 hours after surgery. In this group, patients will be treated with a fast-track protocol of 48 hours. The quality of life and joint function scores are measured before and after surgery at visits.

Category
Treatment - Other

2

Description
Intervention group 2: Patients in this group undergo 96-hour intervention and care approach. In this group, patients will be admitted 24 hours before and 72 hours after surgery. In this group, patients will be treated with routine ward protocols. The quality of life and joint function scores are measured before and after surgery at visits.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani Hospital

Full name of responsible person
Mehdi Motififard

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

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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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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 Motififard

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

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Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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