

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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)

##### Phone

+98 83 3837 1582

##### Email address

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**

Isfahan

**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

#### Street address

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

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Isfahan

#### Province

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#### Postal code

8174673461

#### Phone

+98 31 3668 0042

#### Email

motififard@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

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#### Province

Isfahan

#### Postal code

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#### Phone

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#### 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 Motififard

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Orthopedics

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Mehdi Motififard

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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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****Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehdi Motifard

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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