

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of Outcomes of Kinematic Alignment and Mechanical Alignment Techniques in Patients with Bilateral Severe Osteoarthritis Who Underwent Single Surgeon Simultaneous Bilateral Primary Total Knee Arthroplasty

#### Protocol summary

##### Study aim

This study aimed to compare the results of two techniques in TKA in terms of postoperative complications, duration of surgery, postoperative functional outcome, postoperative radiologic outcome.

##### Design

Two arm parallel group randomised trial with double blinded postoperative care and outcome assessment, each group contains 39 patients.

##### Settings and conduct

Cases are selected among the patients of the knee orthopedic clinic of Imam Hossein, medical training center in tehran who are candidates for TKA surgery with a diagnosis of severe bilateral osteoarthritis of the knee. Knee alignment is measured before joint replacement surgery with a 3joint view x-ray. Also, the Oxford Knee Score and Visual Analog Scale Score forms will be completed before and after surgery under the supervision of a physician. Surgery time, infection rate, and range of motion will also be measured after surgery (on each knee)

##### Participants/Inclusion and exclusion criteria

Including criteria: Sever bilateral osteoarthritis Debilitating bilateral knee pain due to osteoarthritis Age<50 Excluding criteria: Sever underlying diseases which make anesthesia impossible Recurrent UTI BMI<20 or BMI>50 History of osteomyelitis around knee Neuropathic arthropathy Active or recent infection other than knee Pain free nonfunctional osteoarthritis Genu Recurvatum due to muscular disorders Disruption in knee extensor mechanism Active or recent knee infection Age>80

##### Intervention groups

Each knee in a patient will underwent different technique (MA or KA)

##### Main outcome variables

Body Mass Index, length of surgery, infection rate, joint range of motion, Western Ontario and McMaster Universities Osteoarthritis Index, Visualized analogue scale Score, Oxford Knee Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201027049159N1**

Registration date: **2020-10-30, 1399/08/09**

Registration timing: **retrospective**

Last update: **2020-10-30, 1399/08/09**

Update count: **0**

##### Registration date

2020-10-30, 1399/08/09

##### Registrant information

##### Name

Keyvan Ramezani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7343 0000

##### Email address

keyvanramezani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2019-03-21, 1398/01/01  
**Actual recruitment start date**  
2017-03-21, 1396/01/01  
**Actual recruitment end date**  
2019-03-21, 1398/01/01  
**Trial completion date**  
2020-09-22, 1399/07/01

#### Scientific title

Comparison of Outcomes of Kinematic Alignment and Mechanical Alignment Techniques in Patients with Bilateral Severe Osteoarthritis Who Underwent Single Surgeon Simultaneous Bilateral Primary Total Knee Arthroplasty

#### Public title

Comparison of MA and KA Techniques in TKA

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Sever bilateral osteoarthritis Debilitating bilateral knee pain due to osteoarthritis Age>50 and age<80

##### Exclusion criteria:

Sever underlying diseases which make anesthesia impossible Recurrent UTI BMI<20 or BMI>50 History of osteomyelitis around knee Neuropathic arthropathy Active or recent infection other than knee Pain free nonfunctional osteoarthritis Genu Recurvatum due to muscular disorders Disruption in knee extensor mechanism Active or recent knee infection

#### Age

From **50 years** old to **80 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

#### Sample size

Target sample size: **70**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Right knee and left knee  
Actual sample size reached: **78**  
More than 1 sample in each individual  
Actual sample size in each individual: **2**  
Right knee and left knee

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Based on random number table, patients divided in to two groups, in first one, right knee will be replaced by kinematic technique and left knee will be replaced by mechanical technique and in the second group right knee will be replaced by mechanical technique and left knee will be replaced by kinematic technique.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Patients and their caregivers do not know which technique is used for each knee. Beside the main surgeon, neither medical team members nor research team members do not know which technique is used for each knee. Statistics consultant does not know which technique is used for each knee.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

No 1, Koodakyar alley, Daneshju Blvd, Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2020-10-27, 1399/08/06

#### Ethics committee reference number

IR.SBMU.MSP.REC.1399.381

## Health conditions studied

### 1

#### Description of health condition studied

Knee osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Knee functional score on the Oxford Knee Questionnaire

#### Timepoint

Before surgery, 1, 3, 6, 12 month after surgery

#### Method of measurement

Oxford Knee Score Questionnaire

## 2

### **Description**

Pain rate based on Visual Analogue Scale

### **Timepoint**

Before surgery, 1, 3, 6, 12 month after surgery

### **Method of measurement**

Visual Analogue Scale questionnaire

## 3

### **Description**

Knee Range of Motion

### **Timepoint**

Before surgery, 1, 3, 6, 12 month after surgery

### **Method of measurement**

Goniometer

## 4

### **Description**

Rate of knee joint infection after surgery

### **Timepoint**

1, 3, 6, 12 month after surgery

### **Method of measurement**

Clinical evaluation and CRP (C-reactive protein) and ESR ((Erythrocyte Sedimentation Rate) level

## 5

### **Description**

Duration of surgery

### **Timepoint**

After surgery

### **Method of measurement**

Duration of tourniquet time in minutes

## 6

### **Description**

Score based on Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

### **Timepoint**

Before surgery, 1, 3, 6, 12 month after surgery

### **Method of measurement**

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The first group is the group in which the right knee is replaced by Kinematic alignment method and the left knee is replaced by Mechanical alignment method. In general, the classic method of knee replacement is called mechanical alignment method, which has been used since the 20th century,

but since the early third millennium, Kinematic Alignment method was also introduced. In this study, we compare the results of these two methods. In both methods, Zimmer's primary total knee arthroplasty prosthesis are used. The basis of the mechanical method is to create an alignment along the overall mechanical axis of the limb. The surface of the knee joint in this method is perpendicular to the mechanical axis of the limb, but in fact even in people without osteoarthritis of the knee and without symptoms of pain and limited movement of the knee, the surface of the knee joint is not perpendicular to the mechanical axis of the limb, but the knee inherently It is slightly in the varus, so in the kinematic method our goal is to establish the overall alignment of the limb and the knee joint based on the patient's native position before osteoarthritis (not necessarily to adjust the joint surface perpendicular to the mechanical axis of the limb) and this is concept of the kinematic method.

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Intervention group: The second group is the group in which the right knee is replaced by Mechanical alignment method and the left knee is replaced by Kinematic alignment method. In general, the classic method of knee replacement is called mechanical alignment method, which has been used since the 20th century, but since the early third millennium, Kinematic Alignment method was also introduced. In this study, we compare the results of these two methods. In both methods, Zimmer's primary total knee arthroplasty prosthesis are used. The basis of the mechanical method is to create an alignment along the overall mechanical axis of the limb. The surface of the knee joint in this method is perpendicular to the mechanical axis of the limb, but in fact even in people without osteoarthritis of the knee and without symptoms of pain and limited movement of the knee, the surface of the knee joint is not perpendicular to the mechanical axis of the limb, but the knee inherently It is slightly in the varus, so in the kinematic method our goal is to establish the overall alignment of the limb and the knee joint based on the patient's native position before osteoarthritis (not necessarily to adjust the joint surface perpendicular to the mechanical axis of the limb) and this is concept of the kinematic method.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam hossein hospital

##### **Full name of responsible person**

Mohammad Mahdi Sarzaeem

**Street address**

Nezamabad

**City**

Thran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Email**

keyvanramezani@gmail.com

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

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**City**

Tehran

**Province**

Tehran

**Postal code**

1646734861

**Phone**

+98 21 7343 0000

**Fax****Email**

keyvanramezani@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

No. 1, koodakyar alley, Daneshju Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 23871

**Email**

zarghi@sbmu.ac.ir

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

No

**Title of funding source**

Shahid Beheshti Medical University

**Proportion provided by this source**

1

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Keyvan Ramezani

**Position**

Resident

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Keyvan Ramezani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Nezamabad

**City**

Tehran

**Province**

Tehran

**Postal code**

1646734861

**Phone**

+98 21 7343 0000

**Fax****Email**

keyvanramezani@gmail.com

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Keyvan Ramezani

**Position**

Resident

**Latest degree**

Medical doctor

**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 personal data of study participants can be shared after unidentification.

### **When the data will become available and for how long**

Once the data is collected and analyzed, permanent access is possible.

### **To whom data/document is available**

Access to data is available to all health researchers.

### **Under which criteria data/document could be used**

All data and documents can be published and used in the field of health research by mentioning the source.

### **From where data/document is obtainable**

For receiving all data and information, researchers could contact me on: 00989126083107  
keyvanramezani@gmail.com

### **What processes are involved for a request to access data/document**

Data will be provided to researchers within 1 month of their request.

### **Comments**