

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison of one year outcomes of total knee arthroplasty with Kinematic alignment and mechanical alignment

#### Protocol summary

##### Study aim

Comparison of one-year outcomes of Total Knee Arthroplasty with Kinematic alignment and Mechanical Alignment regarding functionality and patient satisfaction in knee osteoarthritis patients

##### Design

Two-arm parallel-group, non-randomized, one-side blinded clinical trial on 72 patients

##### Settings and conduct

This one-sided, blinded orthopedic clinical trial will be conducted on osteoarthritis patients with two or 3-compartment involvement who have not responded to conservative treatment and are referred to Emam Hossein Hospital in 2022. Patients are classified into two groups, the control group was treated with the mechanical alignment technique, and the case group will be treated with the kinematic alignment technique. Functionality and patient satisfaction within one year of the operation will be assessed using WOMAC, OKS, physical examination, and imaging investigations.

##### Participants/Inclusion and exclusion criteria

Knee osteoarthritis patients with two or 3-compartment involvement who have not responded to conservative treatment are included in this study. Patients with a body mass index (BMI) above 40, a history of knee joint infection, osteoarthritis following trauma in the adjacent bones, bone osteotomy, underlying rheumatologic disease, and patients who did not cooperate or did not give their consent were excluded from the study.

##### Intervention groups

In this study, the intervention was conducted by using the kinematic alignment technique on 36 osteoarthritis patients with two or 3-compartment involvement who have not responded to conservative treatment

##### Main outcome variables

Use of better functioning knee arthroplasty techniques;  
Use of more patient-satisfying knee arthroplasty techniques

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221015056185N1**

Registration date: **2022-10-24, 1401/08/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-10-24, 1401/08/02**

Update count: **0**

##### Registration date

2022-10-24, 1401/08/02

##### Registrant information

##### Name

Mohammadmahdi Omidian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7343 3000

##### Email address

omid\_medicine@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-23, 1401/06/01

##### Expected recruitment end date

2022-12-21, 1401/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of one year outcomes of total knee arthroplasty with Kinematic alignment and mechanical alignment

#### Public title

Comparison of total knee arthroplasty outcomes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Osteoarthritis of the knee with 2 compartments involvement unresponsive to conservative therapy  
Osteoarthritis of the knee with 3 compartments involvement unresponsive to conservative therapy

##### Exclusion criteria:

BMI above 40  
History of infection in the knee  
Osteoarthritis development after trauma to the bones around the knee  
Osteotomy  
Underlying rheumatological disease  
The patient not having consent  
The patient not being cooperative

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 72

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The patients are not informed of the study group they are assigned to; however, the surgeon and the research team know about the patients' assignment.

#### 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

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

##### City

Tehran

#### Province

Tehran

#### Postal code

1983963113

#### Approval date

2022-09-20, 1401/06/29

#### Ethics committee reference number

IR.SBMU.MSP.REC.1401.279

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis of knee

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Annually

#### Method of measurement

WOMAC index

### 2

#### Description

Movement of limitation

#### Timepoint

Annually

#### Method of measurement

WOMAC index

### 3

#### Description

Physical function

#### Timepoint

Annually

#### Method of measurement

WOMAC index

### 4

#### Description

Declared condition

#### Timepoint

Annually

#### Method of measurement

نمره OKS

### 5

#### Description

range of motion

**Timepoint**

annually

**Method of measurement**

Physical examination

**6****Description**

Joint stability

**Timepoint**

Annually

**Method of measurement**

Physical examination

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: kinematic alignment (In this method, the purpose is reconstructing the knee joint in congenital and pre-disease alignment. In other words, the osteotomy is in a way in which the congenital alignment is rebuilt.)

**Category**

Treatment - Surgery

**2****Description**

Control group: mechanical alignment (In this method, the osteotomy is vertical to the mechanical axis of femur and tibia. Therefore a zero degree without varus or valgus is built.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam Hossein Medical center

**Full name of responsible person**

Mohammad Mahdi Omidian

**Street address**

Madani Avenue, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Email**

omid\_medicine@yahoo.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**

5th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2243 9780

**Email**

zarghi@sbmu.ac.ir

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Mahdi Omidian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Madani Avenue, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Email**

omid\_medicine@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Mahdi Omidian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Madani Avenue, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Email**

omid\_medicine@yahoo.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Mahdi Omidian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Madani Avenue, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 3000

**Email**

omid\_medicine@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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

**Title and more details about the data/document**

In this study, data will be sharable after making it anonymous, upon request.

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

Data can be shared, 3 months following publication upon request.

**To whom data/document is available**

University and research centers researchers can use the shared data.

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

The data will be shared with researchers for research and academic purposes.

**From where data/document is obtainable**

Access to data will be through the correspondent author by email communication.

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

Following submission for access to data, according to the correspondent judgment, the request will be assessed in a research team meeting, and if accepted, the data will be presented after becoming anonymous.

**Comments**