

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison results of Kinematic align and Mechanical align knee arthroplasty in patients with osteoarthritis

#### Protocol summary

##### Summary

This randomized trial was conducted on 90 patients with Osteoarthritis of the knee. People with knee Osteoarthritis were included and people with bilateral knee surgery, drug addicts, need for blood transfusions before surgery and had a knee infection were excluded from the study. Patients were divided into two groups of 45 people, in the intervention group, surgery was performed Kinematic align and in the control group, surgery was performed Mechanical align. This study was conducted during the years 1391 to 1392 which then patients were followed up 1 to 3 years. Postoperative pain, day hospitalization, patient satisfaction with the surgery, knee range of motion and hemoglobin before and after surgery was measured and after a year of surgery for patients completed Lyshlom knee scoring scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303286497N4**  
Registration date: **2015-07-24, 1394/05/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-24, 1394/05/02

##### Registrant information

##### Name

Mahmood Karimi Mobarakeh

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1272 2988

##### Email address

m\_karimi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison results of Kinematic align and Mechanical align knee arthroplasty in patients with osteoarthritis

##### Public title

Comparison results of the Kinematic and Mechanical align in the total knee arthroplasty

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients diagnosed with Osteoarthritis of the knee joint with the informed consent  
Exclusion criteria: Patients who need blood transfusions before surgery; Bilateral knee surgery; Knee infection; Fracture during surgery were requiring fixation; Patients with charcot joint; Drug addict

##### Age

No age limit

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 90

## Randomization (investigator's opinion)

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

Kerman Medical University of Ethics Committee

##### Street address

Jomhoori Islami Boulevard

##### City

Kerman

##### Postal code

7519813159

#### Approval date

2013-06-06, 1392/03/16

#### Ethics committee reference number

92/316/K

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis

#### ICD-10 code

M25.7

#### ICD-10 code description

Osteophyte

## Primary outcomes

### 1

#### Description

Hemoglobin

#### Timepoint

Before and after surgery

#### Method of measurement

Recorded from File

### 2

#### Description

Days of hospitalization

#### Timepoint

post operation

#### Method of measurement

Questionnaire

### 3

#### Description

Pain

#### Timepoint

Post operation

#### Method of measurement

Visual Analg Scale

### 4

#### Description

Satisfaction

#### Timepoint

One year after operation

#### Method of measurement

Question of patient

### 5

#### Description

Time abandon the Waker and driving

#### Timepoint

One year after operation

#### Method of measurement

Question of patient

### 6

#### Description

Duration of surgery

#### Timepoint

Post operation

#### Method of measurement

Recorded from File

### 7

#### Description

knee score

#### Timepoint

One year after surgery

#### Method of measurement

Lyshlom score

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

One year after surgery

#### Method of measurement

Recorded from file

## Intervention groups

### 1

#### Description

Kinematic align Knee arthroplasty in the intervention  
Which is less soft tissue release

#### Category

Treatment - Surgery

### 2

#### Description

Mechanical align knee arthroplasty in control group

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shafa Hospital

##### Full name of responsible person

Mahmood Karimi Mobarke

##### Street address

Shafa Street, Kerman, Iran

##### City

Kerman

### 2

#### Recruitment center

##### Name of recruitment center

Razeea Firous Hospital

##### Full name of responsible person

Mahmood Karimi Mobarke

##### Street address

MotaharyStreet, Kerman, Iran

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Abbas Pardakhti

##### Street address

Ibn Sina Street, Somayeh Crossroads

##### City

Kerman

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kerman University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Mahmood Karimi Mobarakeh

##### Position

Associated Professor

##### Other areas of specialty/work

##### Street address

Street Gharani, shahid Bahonar hospitals

##### City

Kerman

##### Postal code

751437896543098

##### Phone

+98 34327229

##### Fax

+98 34327229

##### Email

drkarimi\_m@yahoo.com

##### Web page address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Mahmood Karimi Mobarakeh

##### Position

Associated Professor

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## Person responsible for updating data

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*