Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mahmood Karimi Mobarakeh
Name of organization / entity
Kerman University of Medical Sciences
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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 Boulvard
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
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MotaharyStreet, Kerman, Iran
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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
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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