Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 osteomielitis 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 osteomielitis 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 devided 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 no 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

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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 methid 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 methid 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
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Full name of responsible person
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Position
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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 recieving 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