

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Bi unicondylar knee arthroplasty versus Total knee arthroplasty: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of radiological characteristics and postoperative outcome between those who underwent total knee arthroplasty (TKA) on the leg with the most pain and those who underwent bi unicondylar knee arthroplasty (bi-Uka) on the leg with the most pain.

Design

randomly divided into two groups, TKA and bi-unicondylar knee arthroplasty, using the block randomization method. In one group, the leg that has the most pain is subjected to TKA operation. The other group, the leg that has the most pain, is subjected to bi-UKA operation. Demographic, radiological, and laboratory characteristics will be compared between the two groups. follow up After 1 month and 6 months from the last operation,

Settings and conduct

Imam Hussein Hospital Medical Center -Tehran

Participants/Inclusion and exclusion criteria

Patients with medial and lateral OA suitable for treatment with standard unrestricted TKA, with intact cruciate ligaments (based on radiological evidence and clinical examination), and willing and able to provide informed consent were eligible for inclusion. Rheumatoid or other inflammatory arthropathy, varus or valgus deformity greater than 15 degrees, or flexion contracture greater than 10 degrees, single-compartment OA suitable for isolated UKA, or radiological evidence of patellar OA. Patients with previous knee surgery, those with significant OA of the spine or other lower extremity joints If a clear ligament injury is observed, which makes the condition unfavorable for bi-uka surgery, the patient is excluded from the study.

Intervention groups

TKA method, which replaces the distal femur with a distal femur prosthesis, and bi-uka method, which by reducing the Unnecessary removal .

Main outcome variables

Radiological characteristics and postoperative outcome
Comparison of operation length, operation difficulty,

post-operation hemoglobin drop, complications.
Comparison of filled questionnaires

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230926059523N1**

Registration date: **2023-11-30, 1402/09/09**

Registration timing: **prospective**

Last update: **2023-11-30, 1402/09/09**

Update count: **0**

Registration date

2023-11-30, 1402/09/09

Registrant information

Name

ali ghaneitehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

alighaneitehrani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-08-15, 1403/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bi unicondylar knee arthroplasty versus Total knee arthroplasty: A Randomized Clinical Trial

Public title

Bi unicondylar knee arthroplasty versus Total knee arthroplasty: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with medial and lateral OA suitable for treatment with standard unrestricted TKA Healthy cruciate ligaments (based on radiological evidence and clinical examination) Willing and able to provide informed consent

Exclusion criteria:

Patients with rheumatoid arthritis or other inflammatory arthropathy Varus or valgus deformity greater than 15 degrees Flexion contracture greater than 10 degrees Single-compartment OA suitable for isolated UKA Radiological evidence of Kelgren and Lawrence grade III OA of the patellar joint Patients who had undergone previous knee surgery that might affect the outcome of the arthroplasty, such as anterior or posterior cruciate ligament reconstruction Who had significant OA of the spine or other lower extremity joints were not included in the study Despite the diagnostic measures before the operation, if there is a clear ligament damage that makes the condition unfavorable for bi-uka surgery, the patient will be excluded from the study.

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients included in the study will be randomly divided into two groups, TKA and bi-uncondylar knee arthroplasty, using the block randomization method. First, the leg that has the most pain is subjected to TKA. The other category of foot that has the most pain is subjected to bi-UKA operation. Demographic, radiological, and laboratory characteristics will be compared between the two groups. After 1 month and 6 months from the last operation, the patient is followed up with frequent visits. And questionnaires related to patient function and pain will be filled for both legs. Then, a comparison will be made between the two groups as well as between the two models

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**

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

Street address

Shahid Chamran Highway - Yemen St. - Shahid Abbas Arabi St. (Parvaneh) - next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences and Health Care Services - Headquarters Building 2 - 5th Floor - Vice President of Research and Technology

City

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Province

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Postal code

1985717443

Approval date

2023-09-10, 1402/06/19

Ethics committee reference number

ir.sbm.u.retech.rec.1402.311

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis - knee joint replacement

ICD-10 code

M17.10

ICD-10 code description

Unilateral primary osteoarthritis, unspecified knee

Primary outcomes**1****Description**

KOOS (knee injury and osteoarthritis outcome) questionnaire score including daily activity, sports activity, pain, quality of life, symptoms and joint stiffness before and after surgery

Timepoint

After 1 month and 6 months from the last operation, the patient is followed up with frequent visits. And questionnaires related to patient function and pain will be filled for both legs.

Method of measurement

Clinical records, pre- and post-surgery graphs, lab tests, questionnaires

Treatment - Surgery

Secondary outcomes

1

Description

blood loss during and after surgery

Timepoint

Before, 1 day and 1 week after the operation

Method of measurement

Laboratory data

2

Description

Duration of surgery

Timepoint

During the operation, from the time of skin incision to wound closure

Method of measurement

clock

3

Description

Anatomical and mechanical angles and alignment of the knee joint

Timepoint

Before and after surgery

Method of measurement

standing 3-joint Alignment view graphs (hip-knee-ankle)

Intervention groups

1

Description

Intervention group: The leg that has the most pain is subjected to bi-UKA operation in such a way that the medial and lateral condyles of the knee are replaced with unicondylar prostheses and the anterior cruciate ligament is not damaged. (bi unicondylar knee arthroplasty) in this method. While preserving the cruciate ligament, only the medial and lateral condyles that are damaged in the arthritic process are replaced with medial and lateral unicondylar prostheses (an improved process for both condyles, compared to what is done in UKA), in order to establish proper alignment. joint, the process of replacing the joint with less damage to the healthy ligament structure (ACL) and with the aim of improving the performance of patients after surgery.

Category

Treatment - Surgery

2

Description

Control group: The leg that has the most pain is subjected to TKA

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital Medical Center - Tehran

Full name of responsible person

Mohammad Mahdi Sarzaeem

Street address

Madani Street, Tehran, Iran

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alighaneitehrani@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr afshin zarghi

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Shahid Chamran Highway - Yemen St. - Shahid Abbas Arabi St. (Parvaneh) - next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences and Health Care Services - Headquarters Building 2 - 5th Floor - Vice President of Research and Technology

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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

ali ghanei tehrani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Individual data of participants including radiological angles, scores of questionnaires

When the data will become available and for how long

The access period starts 1 year after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Determining a treatment plan and modeling to perform a similar action in patients who benefit more from bi-UKA

From where data/document is obtainable

Contact by email alighaneitehrani@sbm.ac.ir

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

Sending an e-mail, introducing the organization or responsible person, expressing the work context and goals of accessing information and sending data within a period of 3-6 weeks

Comments