Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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-uncondylar 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
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-09-10, 1402/06/19

Ethics committee reference number
ir.sbmu.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

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 Aligment 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
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein Hospital Medical Center - Tehran
Full name of responsible person
Mohammad Mahdi Sarzaeem
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Madani Street, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Dr afshin zarghi
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hahid 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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4631- 19395
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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

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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@sbmu.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