Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Investigating the functional outcomes of using medial congruent prostheses and comparing its results with Persona's posterior-stabilized prostheses in total knee arthroplasty in patients: A double-blind randomized clinical trial study

Protocol summary

Study aim
This study aims to investigate the functional results and postoperative pain in the use of medial congruent (MC) prostheses and compare the results with Persona's posterior-stabilized (PS) prostheses. Our hypothesis is that the use of the MC prosthesis will provide similar functional and postoperative pain results to the PS prosthesis.

Design
Two-arm parallel group randomized double-blind clinical trial on 80 TKA candidate patients from October 1402 to 1404 in Tehran Shariati Hospital with at least one-year follow-up

Settings and conduct
Tehran Shariati Hospital Patients, the person responsible for randomization, and the person responsible for data analysis will only be aware of each person belonging to one of the groups A and B. They will not know which of the intervention or control groups each of the two groups, A and B, represents. Unlike the above people, the surgical team will know which of the intervention or control groups each of groups A and B belong to.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Patients with severe end-stage osteoarthritis of the knee who are eligible for TKA surgery - Patients with osteoarthritis resistant to conservative treatment Exclusion criteria: - Previous hip or ankle replacement - Rheumatoid Arthritis - Active infections, local or systemic - Osteotomy or previous fracture or surgery of the tibia or femur

Intervention groups
Patients will be assigned to the following two groups: 1. Medial Congruent 2. Persona Posterior-Stabilized In each group, patients will undergo TKA surgery using the mentioned prostheses. All patients will have the same preoperative education, the same preoperative evaluations, and the same postoperative care protocol.

Main outcome variables
Alignment of limbs and prostheses; total surgery time; the total amount of intraoperative bleeding; Hb changes; performance improvement; Complications of surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191222045857N2**
Registration date: **2023-08-18, 1402/05/27**
Registration timing: **prospective**

Last update: **2023-08-18, 1402/05/27**
Update count: **0**

Registration date
2023-08-18, 1402/05/27

Registrant information
Name
Fardis Vosoughi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-07, 1402/07/15

Expected recruitment end date
2025-10-02, 1404/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the functional outcomes of using medial congruent prostheses and comparing its results with Persona's posterior-stabilized prostheses in total knee arthroplasty in patients: A double-blind randomized clinical trial study

Public title
Comparing the functional results of Persona's medial congruent and posterior-stabilized prostheses in total knee arthroplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with severe end-stage osteoarthritis of the knee who are eligible for TKA surgery (painful and disabled knee joint with involvement of one or more compartments) Patients with osteoarthritis resistant to conservative treatment
Exclusion criteria:
Previous hip or ankle replacement Rheumatoid Arthritis Active infections, local or systemic Osteotomy or previous fracture or surgery of the tibia or femur
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into control (persona posterior-stabilized prostheses) and intervention (congruent medial prostheses) groups. The randomization of people will be done using the Permuted block randomization method with the random selection of the size of the blocks. Block randomization works by randomizing participants within blocks such that an equal number is assigned to each treatment. For example, given a block size of 4, there are six possible ways to equally assign participants to a block. Allocation proceeds by randomly selecting one of the orderings and assigning the next block of participants to study groups according to the specified sequence. Furthermore, the block size must be divisible by the number of study groups. Random Allocation Software 2.0 will be used to generate a random sequence by block method for ease of use and time-saving. A disadvantage of block randomization is that the allocation of participants may be predictable and result in selection bias when the study groups are unmasked. That is, the treatment assignment that has so far occurred least often in the block likely will be the next chosen. Selection bias may be reduced by using random block sizes and keeping the investigator blind to the size of each block.
Blinding (investigator's opinion)
Double blinded
Blinding description
The blinding method in this study is double-blinded, in which the patients, the person responsible for randomization, and the person responsible for data analysis are not aware of the randomization setting of the study. Patients, the person responsible for randomization, and the person responsible for data analysis will only be aware of each person belonging to one of the group's A and B. They will not know which of the intervention or control groups each of the two groups, A and B, represents. Unlike the above people, the surgical team will know which of the intervention or control groups each of groups A and B belongs to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Shariati Hospital - Tehran University of Medical Sciences
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town
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Tehran
Province
Tehran
Postal code
1419943471
Approval date
2023-07-19, 1402/04/28
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.070

Health conditions studied

1

Description of health condition studied
Severe end-stage knee osteoarthritis eligible for TKA surgery
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Alignment of limbs and prostheses
Timepoint
Patients visit the clinic for evaluation at 2, 6, 12 and 6 months of age and then annually after surgery. Knee radiographs including AP and lateral views will be taken.
Method of measurement
A long standing radiograph of the knee leg at 3 months after surgery will be used to evaluate the hip-knee-ankle angle (HKA; mechanical axis) of the lower limb, the varus and/or valgus angle of the femur relative to the mechanical axis of the femur. (medial femoral distal angle; MDFA), and the varus and/or valgus angle of a tibial component relative to the mechanical axis of the tibia (medial proximal tibial angle). A lateral radiograph will be used to assess the flexion of the femoral component (femoral flexion angle) and the tilt of the tibial component (tibial tilt).

Secondary outcomes

1

Description
Total surgery time
Timepoint
From skin incision to wound closure from arthrotomy site repair, vacuum drain placement and skin closure
Method of measurement
Based on the time measured by the stopwatch

2

Description
The total amount of intraoperative bleeding
Timepoint
From skin incision to wound closure from arthrotomy site repair, vacuum drain placement and skin closure
Method of measurement
The amount of blood collected by the suction device

3

Description
Hb changes
Timepoint
Before and 24 hours after the operation
Method of measurement
CBC, diff

4

Description
Blood transfusion rate
Timepoint
Hospitalization period
Method of measurement
Counting the number of blood units injected

5

Description
Improve performance
Timepoint
Weeks 2, 6, 12 and 6 months and 1 year after surgery
Method of measurement
Visual Analog Scale pain score - Knee Injury and Osteoarthritis Outcome Score - Forgotten Joint Score - Range of motion

6

Description
Complications of surgery
Timepoint
During one year after the operation
Method of measurement
History and examination

Intervention groups

1

Description
Intervention group: There are patients in whom knee joint replacement surgery is performed using medial congruent prostheses. This group will have the same pre-operative training, pre-operative evaluations and post-operative care as the control group.
Category
Treatment - Surgery

2

Description
Control group: There are patients in whom knee joint replacement surgery is performed using Persona Posterior-Stabilized prostheses. This group will have the same pre-operative training, pre-operative evaluations and post-operative care as the intervention group.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Fardis Vosoughi
Street address

North Kargar St., Jalal Al-Ahmad Three Ways, Opposite the Faculty of Economics, Dr. Shariati Research and Treatment Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Akbar Fotouhi

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Vice Chancellor for Research and Technology, Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fardis Vosoughi

Position
Assistant Professor of Orthopedics

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable