

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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Iran (Islamic Republic of)

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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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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

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North Kargar St., Jalal Al-Ahmad Three Ways,
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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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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