Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of a new generation rotational prosthesis compared to a standard prosthesis in primary arthroplasty of severely deformed knees: A Randomized Clinical Trial

Protocol summary

Study aim

determination of the efficacy, safety, clinical performance, and cost-effectiveness of a domestically manufactured rotating-hinge knee prosthesis compared with an imported prosthesis in patients with severe knee deformity undergoing total knee arthroplasty.

Design

A randomized, controlled, parallel-group, double-blind clinical trial will be conducted in 30 patients. Randomization will be performed using (sealedenvelope.com).

Settings and conduct

Eligible patients will be identified through selected orthopedic clinics and randomly allocated in a 1:1 ratio to receive either the Osveh prosthesis or an imported PS prosthesis. All participants will undergo standardized total knee arthroplasty with identical anesthesia and postoperative care protocols. Follow-up assessments will be conducted at 2, 4, and 6 months after surgery. The primary outcome will be the change in the Knee Function Index score, and the collected data will be analyzed accordingly.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients aged 50–80 years with knee osteoarthritis confirmed by the treating surgeon, who provide written informed consent to participate in the study. Exclusion criteria: Patients with a history of previous knee surgery or knee infection, those requiring knee surgery, and those with uncontrolled underlying medical conditions.

Intervention groups

In the intervention group, patients will undergo total knee arthroplasty using a domestically manufactured, advanced-design rotating-hinge knee prosthesis. In the control group, patients will undergo total knee arthroplasty using a routinely used imported knee prosthesis.

Main outcome variables

Surgical site infection;Range of motion (ROM);Functional outcomes;Postoperative complications;Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260425069152N2**
Registration date: **2026-10-17, 1405/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-17, 1405/07/25**
Update count: **0**

Registration date

2026-10-17, 1405/07/25

Registrant information

Name

Sanaz Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-10-11, 1405/07/19

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of a new generation rotational prosthesis compared to a standard prosthesis in primary arthroplasty of severely deformed knees: A Randomized Clinical Trial

Public title
Evaluation of the effect of a new generation rotational prosthesis compared to a standard prosthesis in primary arthroplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of primary or secondary knee osteoarthritis with severe deformity, defined as varus deformity >15°, valgus deformity >20°, or a flexion contracture >30° Clinically significant instability of the collateral ligaments (MCL or LCL), as confirmed by the treating surgeon Failure of conservative treatment, accompanied by severe pain and functional limitations Provision of written informed consent to participate in the study
Exclusion criteria:
Acute or emergency knee surgery. History of localized or systemic knee infection. History of previous knee surgery. Uncontrolled underlying medical conditions, such as diabetes mellitus (which may lead to impaired immune function), neuromuscular disorders affecting lower-extremity function (e.g., severe peripheral neuropathy or sequelae of stroke), severe renal impairment (eGFR <30 mL/min), or severe systemic diseases that would place the patient at high risk during surgery. Patients with immunodeficiency. Severe bone loss requiring the use of bulk structural bone grafts or specialized augments beyond what can be managed with standard prosthetic components. Body mass index (BMI) >40 kg/m². Known allergy to any of the prosthetic components or materials (e.g., titanium, polyethylene, etc.). Unwillingness or inability to attend regular follow-up visits. Injury occurring during the follow-up period due to causes unrelated to the treatment.
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
To achieve equal numbers of participants in the study groups and minimize differences in group sizes, randomization will be performed using permuted block randomization with fixed block sizes of four and a 1:1 allocation ratio. For this purpose, the randomization blocks and allocation sequences will be generated using the Sealed Envelope online randomization service. The allocation sequences will be placed in sequentially numbered, sealed opaque envelopes. Upon enrollment of eligible participants, the envelopes will be opened sequentially according to the predetermined order, and each participant will be assigned to one of the study arms based on the allocation sequence contained in the corresponding envelope. Random allocation of eligible participants will be performed by an individual who is independent of the research team and will have no involvement in the treatment, participant follow-up, data collection, or data recording processes.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be double-blinded with respect to the participants and outcome assessors. Participants will be allocated to the intervention or control group according to the predetermined randomization sequence generated using block randomization. Participants will not be informed of the type of prosthesis used, and the outcome assessors will be blinded to participants' group allocation. Due to the nature of the intervention, the surgeon and members of the surgical team responsible for selecting and implanting the prosthesis cannot be blinded to treatment allocation. If the statistical analysis is performed by an independent statistician, the data from the two groups will be provided using anonymous group codes (e.g., Group A and Group B), allowing the statistical analysis to be conducted without knowledge of the type of prosthesis assigned to each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Imam Reza Hospital
Street address
Imam Reza Educational, Research and Medical Center, Imam Reza Hospital Square, Ibn Sina Street, Mashhad, Razavi Khorasan, Iran
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Mashhad
Province
Razavi Khorasan

Postal code
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Approval date
2026-08-10, 1405/05/19
Ethics committee reference number
IR.MUMS.IRH.REC.1405.146

Health conditions studied

1

Description of health condition studied
Severe Knee Osteoarthritis with Knee Deformity
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
(knee surgery score -KSS)
Timepoint
At baseline, and 2, 4, and 6 months after surgery
Method of measurement
Using the Knee Society Score (KSS) questionnaire

2

Description
surgical site infection
Timepoint
At baseline, and 2, 4, and 6 months after surgery
Method of measurement
Clinical assessment

3

Description
quality of life
Timepoint
At baseline, and 2, 4, and 6 months after surgery
Method of measurement
SF-12 Questionnaire

Secondary outcomes

1

Description
revision rate
Timepoint
6 months post surgery
Method of measurement
clinical assessment

Intervention groups

1

Description
Intervention group: Patients will undergo total knee arthroplasty using a domestically manufactured rotating-hinge knee prosthesis (Osveh Company).
Category
Treatment - Surgery

2

Description
Control group: **Patients receiving a routinely used imported knee prosthesis.**
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Mohammad Hossein Ebrahimzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Osveh Asia Medical Instruments Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sanaz Zabihi
Position
Research assistant
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Additional data doesn't exist
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to

make this available