Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Knee Immobilizer Use on Immediate Postoperative Clinical Outcomes Following Total Knee Arthroplasty

Protocol summary

Study aim
Determining the effect of using an immobilizing knee brace immediately after Total Knee Arthroplasty on the functional and clinical outcomes of hospitalized patients.

Design
Parallel-group RCT, 72 TKA candidates (two groups of 36). Randomization via blocked allocation. Outcome assessor and data analyst are single-blinded. Phase: 3.

Settings and conduct
This research is an RCT conducted at Imam Khomeini Hospital (RA), Urmia. TKA candidates are divided into two groups: Intervention: Use of an extension-locked knee brace for 8 days post-surgery. Control: Standard care without the brace. Outcomes include pain, analgesic use, range of motion, and function, assessed pre-operatively and on days 1, 7, and 14 post-op. The outcome assessor and data analyst are blinded to group allocation (single-blind).

Participants/Inclusion and exclusion criteria
Inclusion: Knee OA patients, TKA candidates, 50+, consenting & cooperative. Exclusion: BMI>40, gait neuromuscular disorders, severe chronic illness, acute surgical complications.

Intervention groups
Intervention Group: Immediately after transfer to the ward, patients receive an Extension-Locked Knee Brace, used for 8 days post-operatively per protocol. Patients receive full training on application and precautions. Control Group: Patients do not receive a knee brace or external support, only standard post-TKA care (pain control, initial rehabilitation, routine physiotherapy). Medication, analgesia protocols, and physiotherapy programs are identical for both groups.

Main outcome variables
The primary outcomes of this study include the assessment of post-operative pain severity using the VAS scale, the amount of opioid analgesic consumption, knee range of motion, patient's functional ability, and the incidence of early post-operative complications such as falls and knee instability.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260408069035N1**
Registration date: **2026-05-24, 1405/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-24, 1405/03/03**
Update count: **0**

Registration date
2026-05-24, 1405/03/03

Registrant information
Name
Farshid Shafavi
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2027-03-20, 1405/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of Knee Immobilizer Use on Immediate Postoperative Clinical Outcomes Following Total Knee Arthroplasty

Public title
splinted knee brace after total knee replacement surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of knee osteoarthritis and candidacy for Total Knee Arthroplasty (TKA) by an orthopedic surgeon Age 50 years or older Informed consent to participate in the study Ability to cooperate with post-operative assessments

Exclusion criteria:
BMI greater than 40 Presence of neuromuscular diseases affecting ambulation. History of severe chronic illnesses (e.g., advanced heart failure, progressive neurological diseases) that impact functional outcomes Occurrence of acute complications during or after surgery that prevent further follow-up Patient’s unwillingness to cooperate at any stage of the study.

Age
From **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized using block randomization with fixed block sizes of four. The random allocation sequence will be generated by computer software, and within each block, patients will be randomly assigned to either Group A or Group B. To prevent selection bias, allocation concealment will be ensured using the SNOSE method (Sequentially Numbered, Opaque, Sealed Envelopes). The random sequence will be placed inside opaque, sequentially numbered, sealed envelopes, which will be opened only after participant enrollment.

Blinding (investigator's opinion)
Single blinded

Blinding description
Following TKA surgery and patient stabilization, participants will be randomly allocated to either the intervention or control group using a randomization table and block randomization. This process will be managed by an independent party using sealed, opaque envelopes. As blinding patients and the treatment team is not feasible, only the outcome assessor and data analyst will be blinded to group allocation to minimize bias (Single-blind).

Placebo
Not used

Assignment
Parallel

Other design features
short-term (8-day) use of a locked-hinged knee brace post-TKA, employing full blinding of outcome assessors and data analysts to mitigate bias, while assessing comprehensive functional and safety outcomes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Urmia University of Medical Sciences - Imam Khomeini University Hospit

Street address
Imam Khomeini University Hospital-Ershad AVE,.Modarres Blvd,. Urmia-IRAN

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5715789397

Approval date
2026-05-13, 1405/02/23

Ethics committee reference number
IR.UMSU.HIMAM.REC.1405.027

Health conditions studied

1

Description of health condition studied
Total Knee Arthroplasty

ICD-10 code
Z96.653

ICD-10 code description
Presence of artificial knee joint, bilateral

Primary outcomes

1

Description
Postoperative pain intensity based on the Visual Analog Scale (VAS)

Timepoint
Postoperative Day 1Postoperative Day 7Postoperative Day 14

Method of measurement
Postoperative pain intensity based on the visual analog scale (VAS) (0-10)

Secondary outcomes

1

Description
Knee Range of Motion
Timepoint
Postoperative Day 1,Postoperative Day 7,Postoperative Day 14
Method of measurement
Goniometer

Intervention groups

1

Description
Patients in this group will be placed in an extension-locked knee brace immediately after transfer to the ward. The intervention protocol includes continuous use of the brace for 8 days after surgery. To ensure adherence to the protocol, the patient will be provided with necessary training on how to properly fasten the brace, duration of use, and safety precautions.
Category
Rehabilitation

2

Description
Control group: Patients in this group will be placed under the Standard of Care protocol and will not use any external support or knee brace. This care includes pain management, medication protocols, initial rehabilitation, and routine physiotherapy programs.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital in Urmia
Full name of responsible person
Dr.Farshid Shafavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Farsh.d Shafavi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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