

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

Name of organization / entity

Country

Iran (Islamic Republic of)

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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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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 1 Postoperative Day 7 Postoperative 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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Imam Khomeini University Hospital, Ershad AVE, Modarres Blvd, Urmia, IRAN

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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. Farshid 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