

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the efficacy and side effects of using lateral screw in high tibial osteotomy

Protocol summary

Study aim

To evaluate the efficacy and complications of using a lateral screw in patients undergoing high tibial osteotomy (HTO).

Design

Double-blind randomized controlled trial (RCT) using permuted block randomization.

Settings and conduct

Conducted at Imam Khomeini Hospital Complex, Tehran. Eligible patients will be enrolled over a 6-month period in 2024. All procedures will be standardized, and follow-ups will be conducted at regular intervals postoperatively.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age over 18 and under 50 years Knee varus deformity with or without medial compartment osteoarthritis (Kellgren-Lawrence grade 3 or 4) Informed consent MPTA (Medial Proximal Tibial Angle) less than or equal to 83 degrees Exclusion Criteria History of previous surgery on the limb Revision surgery Dementia or psychiatric disorders Inflammatory arthritis Use of systemic corticosteroids Uncontrolled diabetes Range of motion less than 90 degrees Varus deformity greater than 15 degrees, flexion contracture greater than 15 degrees, or subluxation greater than 1 cm Severe bone defect in the medial tibia Skin problems at the surgical site Smoking within the past three months Use of NSAIDs up to 6 weeks before surgery Vascular diseases BMI greater than 30 or less than 18

Intervention groups

Group A (Intervention): HTO with insertion of a 6.5 mm partially threaded lateral screw Group B (Control): HTO without lateral screw

Main outcome variables

Time to radiographic union Pain (VAS score) Knee function (WOMAC, IKDC, Lysholm) Postoperative complications (infection, wound issues, osteomyelitis, non-union)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200305046700N6**

Registration date: **2025-05-03, 1404/02/13**

Registration timing: **prospective**

Last update: **2025-05-03, 1404/02/13**

Update count: **0**

Registration date

2025-05-03, 1404/02/13

Registrant information

Name

Mohammadreza Razzaghof

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 0196

Email address

m-razzaghof@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-20, 1404/02/30

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy and side effects of using lateral screw in high tibial osteotomy

Public title

Lateral screw in high tibial osteotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age >18 and <50 Varus knee with or without medial osteoarthritis (Kellgren-Lawrence grade 3-4) Informed consent MPTA \leq 83

Exclusion criteria:

Previous limb surgery Inflammatory arthritis Range of motion < 90° Severe varus >15°, flexion contracture >15°, or tibial subluxation >1 cm Severe medial tibial bone loss (>3 mm)

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization (balanced blocks)

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind — the patient and outcome assessor are blinded. The surgeon is aware of the allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam khomeini hospital complex

Street address

Keshavarz boulevard, Imam khomeini hospital complex

City

Tehran

Province

Tehran

Postal code

6361693794

Approval date

2024-05-07, 1403/02/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1403.512

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Improvement in knee function and pain based on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score.

Timepoint

WOMAC score will be assessed at baseline (preoperative), 6 months after surgery.

Method of measurement

The Persian-validated version of the WOMAC questionnaire will be used. The questionnaire will be self-reported by the patient under supervision of the research team.

Secondary outcomes

1

Description

Pain level during activity using Visual Analog Scale (VAS)

Timepoint

Preoperative, 6 weeks, 12 weeks, 6 months, and 1 year after surgery

Method of measurement

VAS questionnaire (0-10 scale), patient-reported

2

Description

Radiographic union of the osteotomy site after high tibial osteotomy (HTO).

Timepoint

6 weeks, 8 weeks, 10 weeks, 12 weeks, 6 months, and 1 year.

Method of measurement

Radiographic assessment by orthopedic surgeon. Union is confirmed when 3 out of 4 cortices are bridged on standard AP and lateral X-rays and the patient reports

minimal or no pain during full weight-bearing (VAS \leq 2).

3

Description

Time (in weeks) to return to work and athletic activity

Timepoint

Recorded once achieved during follow-up

Method of measurement

Patient interview during follow-up visits

4

Description

Radiological Angles (MPTA, LDFA, PTS, Varus Angle)

Timepoint

Preoperative and last follow-up (6 months or 1 year)

Method of measurement

Radiographic measurement on full-length standing X-rays

Intervention groups

1

Description

Intervention group: HTO with screw

Category

Treatment - Surgery

2

Description

Control group: HTO without screw

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Joint Reconstruction Research Center/ Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Javad Mortazavi

Street address

Joint Reconstruction Research Center, Imam Khomeini Hospital Complex, East Baqer Khan Street, North Chamran Highway

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1586

Email

m.razzaghof@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

Street address

Office of Vice-Chancellor for research, Central Building of Tehran University of Medical Sciences, No. 226, Qods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran Univeristy

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

Mohammadreza Razzaghof

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

No.17, Sheybani Alley, North Jamalzadeh Street

City

Tehran

Province

Tehran
Postal code
1416753955
Phone
+98 21 6658 0196
Fax
Email
m-razzaghof@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Razzaghof
Position
Orthopedic Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No.17, Sheybani Alley, North Jamalzadeh Street
City
Tehran
Province
Tehran
Postal code
1416753955
Phone
+98 21 6658 0196
Fax
Email
m-razzaghof@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Razzaghof
Position
Orthopedic Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No.17, Sheybani Alley, North Jamalzadeh Street
City
Tehran
Province
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Postal code
1416753955
Phone
+98 21 6658 0196
Fax
Email
m-razzaghof@razi.tums.ac.ir

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 further 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available