

# 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 ≤ 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**

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##### **Postal code**

1419733141

##### **Phone**

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##### **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.

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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

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No.17, Sheybani Alley, North Jamalzadeh Street

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##### **Province**

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## Person responsible for scientific inquiries

### Contact

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Mohammadreza Razzaghof  
**Position**  
Orthopedic Resident  
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## Person responsible for updating data

### Contact

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Medical doctor  
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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 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