

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparative study of treatment outcome in patients with anterior cruciate ligament injury undergoing reconstruction surgery with or without distal Kaplan tenodesis: a randomized clinical trial

#### Protocol summary

##### Study aim

To compare treatment outcome in patients with anterior cruciate ligament (ACL) injury undergoing reconstruction surgery with and without distal Kaplan tenodesis

##### Design

Two-arm parallel randomized trial, single-blind, on 60 patients, Single center

##### Settings and conduct

This single-center trial at Imam Khomeini Hospital (Tehran) included ACL-injury patients aged 18–45y candidates for surgery. Using block randomization (block size=4), patients were assigned to ACL reconstruction with or without Kaplan tenodesis. The surgeon was unblinded; patients, evaluator, and analyst were blinded. Follow-up included physical exams and questionnaires.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients aged 18 to 45 years, ACL injury that requires surgery. Exclusion criteria: Revision surgery of the ACL, Need for bilateral ACL reconstruction, Patients requiring simultaneous repair or reconstruction of the posterior cruciate ligament and medial or lateral collateral ligament, Patients with symptomatic articular cartilage defects requiring surgery beyond debridement and an intact lateral meniscus, Patients requiring simultaneous osteotomy

##### Intervention groups

Intervention group: ACL reconstruction with distal Kaplan tenodesis. After ACL reconstruction using hamstring autograft, if internal tibial rotation is observed, distal Kaplan tenodesis is performed. An incision is made in the lateral thigh, a strip is harvested from the Iliotibial Band (ITB), passed over the Lateral Collateral Ligament, and tenodesis is performed at 90 degrees of flexion. Control group: ACL reconstruction without distal Kaplan tenodesis.

##### Main outcome variables

amount of anterior tibial displacement, rotational

stability of the knee joint, IKDC Score, Tegner Activity Scale score, Lysholm score, Pain score, need for reoperation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200305046700N15**

Registration date: **2026-07-23, 1405/05/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2026-07-23, 1405/05/01**

Update count: **0**

##### Registration date

2026-07-23, 1405/05/01

##### 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

**recruiting**

##### Funding source

##### Expected recruitment start date

2025-12-22, 1404/10/01

##### Expected recruitment end date

2028-12-21, 1407/10/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of treatment outcome in patients with anterior cruciate ligament injury undergoing reconstruction surgery with or without distal Kaplan tenodesis: a randomized clinical trial

**Public title**

Effect of Kaplan Tenodesis on ACL Reconstruction Outcomes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Adult patients aged 18 to 55 years Anterior Cruciate Ligament (ACL) injuries that are eligible for surgery

**Exclusion criteria:**

Anterior Cruciate Ligament (ACL) revision surgery need for bilateral ACL reconstruction surgery patients requiring simultaneous repair or reconstruction of the posterior cruciate ligament and medial or lateral collateral ligament, patients with symptomatic articular cartilage defects requiring surgery beyond debridement, and an unhealthy lateral meniscus patients requiring simultaneous osteotomy patients whose contralateral knee is positive for any of the tests including the Anterior Drower test, Posterior Drower test, Lachman test, Pivot shift test, and rotational stability tests that raise suspicion of ligament damage

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be performed using random permuted blocks with fixed size of 4. The sequence will be generated by a random number generator in Excel and placed in numbered, sealed, opaque envelopes. At the time of surgery, the next envelope will be opened by an individual independent of the surgical team, and the patient will be allocated to one of two groups (distal Kaplan tenodesis or no tenodesis) based on the code inside. Allocation concealment is ensured as those involved in recruitment, surgery, and assessment are unaware of the sequence.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, patients, the clinical evaluator, and the data analyst are blinded to the type of procedure (with or without distal Kaplan tenodesis). Only the surgeon is aware of the procedure due to the nature of the intervention. Patients are not informed before surgery and observe no difference in dressings or wound appearance post-operatively. The clinical evaluator has no access to surgical records during 3- and 9-month follow-ups, and patients are instructed not to disclose their procedure type. The data analyst remains blinded until completion of statistical analyses.

**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/ Tehran University of Medical Sciences

**Street address**

Imam Khomeini Hospital Complex, East Baqer Khan Street, North Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Approval date**

2025-05-20, 1404/02/30

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1404.134

**Health conditions studied****1****Description of health condition studied**

Anterior Cruciate Ligament Injury

**ICD-10 code**

S83.51

**ICD-10 code description**

Sprain of anterior cruciate ligament of knee

**Primary outcomes****1****Description**

the amount of anterior tibial displacement

## **Timepoint**

3 months and 9 months after surgery.

## **Method of measurement**

Lachman test

## **2**

### **Description**

rotational stability of the knee joint

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

pivot shift test

## **3**

### **Description**

the lysholm questionnaire score

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

Lysholm knee questionnaire

## **4**

### **Description**

IKDC (International Knee Documentation Committee) score

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

International Knee Documentation Committee (IKDC) Questionnaire

## **5**

### **Description**

Tegner Activity Scale (TAS) score

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

Tanger Activity Score Questionnaire

## **6**

### **Description**

VAS (Visual Analogue Scale) score

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

Visual Analog Scale (VAS) questionnaire

## **7**

### **Description**

The exact amount of anterior tibial displacement based on the KT-1000 test grade

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

KT1000 Arthrometer

## **8**

### **Description**

the need for reoperation

### **Timepoint**

3 months and 9 months after surgery.

### **Method of measurement**

Surgeon Evaluation and Examination

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Group undergoing Kaplan Tendonectomy after ACL reconstruction. For distal Kaplan tenodesis surgery, a 10-centimeter incision is made on the distal and lateral aspect of the thigh, at the mid-portion of the iliotibial band (ITB), with a slight inclination toward Gerdy's tubercle. Then, a 10 × 1 centimeter strip of the ITB is incised. The proximal portion is detached, while the distal portion remains attached to the tibia at Gerdy's tubercle. After preparing the graft, an appropriate reamer is used to create a tunnel in the femur. Finally, the graft is passed over the lateral collateral ligament (LCL), preserving the superior lateral genicular artery, and tenodesis of the graft is performed at 90 degrees of knee flexion and in a neutral rotation position.

#### **Category**

Treatment - Surgery

### **2**

#### **Description**

Control group: Group undergoing ACL reconstruction only (Without Kaplan Tenodesis)

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

imam khomeini hospital complex

##### **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 6119 0000  
**Fax**  
+98 21 6658 1625  
**Email**  
smjmort@yahoo.com  
**Web page address**  
<https://ikhc.tums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr Ramin Kordi  
**Street address**  
Vice-Chancellor for Research and Technology Central  
Building of Tehran University of Medical Sciences, No.  
226, Qods St., Keshavarz Blvd.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۱۹۷۳۳۱۴۱  
**Phone**  
+98 21 8163 3686  
**Fax**  
+98 21 6658 1625  
**Email**  
ramin\_kordi@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?

Yes

#### Title of funding source

Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Razzaghof

**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
No.17, Sheybani Alley, North Jamalzadeh Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1419733141  
**Phone**  
+98 21 6658 0196  
**Fax**  
+98 21 6658 1625  
**Email**  
m.razzaghof@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Razzaghof  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
No.17, Sheybani Alley, North Jamalzadeh Street  
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**Postal code**  
1419733141  
**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**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics

**Street address**

No.17, Sheybani Alley, North Jamalzadeh Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**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**

No decision yet

**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