

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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
City
Tehran
Province
Tehran
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