Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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Imam Khomeini Hospital Complex, East Baqerkhan Street, North Chamran Highway
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Tehran
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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
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1

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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
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

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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
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