Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

Evaluation of the clinical outcomes of anterior cruciate ligament reconstruction alone compared to anterior cruciate ligament reconstruction combined with iliotibial band tendon grafting using the Arnold and Coker method and modified iliotibial band tendinosis using the Lemaire method in patients with anterior cruciate ligament rupture.

Protocol summary

Study aim

Comparison of clinical outcomes of anterior cruciate ligament reconstruction alone with anterior cruciate ligament reconstruction combined with anterolateral ligament/iliotibial band repair using two different surgical techniques (Arnold and Coker, and modified Lemaire) in patients with anterior cruciate ligament rupture

Design

Clinical trial, parallel groups, unblinded, on 48 patients, non-randomized

Settings and conduct

This open-label clinical trial will be conducted at Shohada Tajrish Hospital. Patients with anterior cruciate ligament rupture will be divided into three groups at the discretion of the surgeon: 1) ACL reconstruction with anterolateral ligament reconstruction using the Arnold and Coker method, 2) ACL reconstruction with modified iliotibial band tendinosis using the Lemaire method, 3) ACL reconstruction alone. Patients will be evaluated for clinical and functional outcomes one year after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with anterior cruciate ligament rupture who have a positive Pivot Shift test and a Pivot Shift score of 3. Exclusion criteria: knee osteoarthritis, simultaneous injury to multiple ligaments.

Intervention groups

Group 1: Patients undergo anterior cruciate ligament reconstruction along with anterolateral ligament reconstruction using the Arnold and Coker method using an iliotibial band graft to increase lateral knee stability. Group 2: Patients undergo anterior cruciate ligament reconstruction along with modified iliotibial band tendinosis using the Lemaire method, in which the iliotibial band is used to reconstruct and enhance knee stability. Group 3: Patients undergo anterior cruciate ligament reconstruction only using the standard method, without intervention on the anterolateral ligament or iliotibial band.

Main outcome variables

Knee score, quality of life, knee function

General information

Reason for update

To enhance the scientific rigor of the study and provide a more accurate answer to the research question, a third group of patients undergoing anterior cruciate ligament (ACL) reconstruction without anterolateral ligament (ALL) reconstruction was added to the protocol. This change enables a direct comparison of the results of ACL reconstruction alone with those of ACL reconstruction combined with anterolateral ligament reconstruction using two different methods (Arnold-Coker and Lemire). Thus, the study was upgraded from a two-group to a three-group design, increasing the power of comparative analysis. Other parts of the protocol, including entry/exclusion criteria, ACL surgical technique, and rehabilitation protocol, remained unchanged.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250307064959N1**
Registration date: **2025-04-08, 1404/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-26, 1404/07/04**
Update count: **1**

Registration date

2025-04-08, 1404/01/19

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-03-10, 1403/12/20
Expected recruitment end date
2026-03-11, 1404/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the clinical outcomes of anterior cruciate ligament reconstruction alone compared to anterior cruciate ligament reconstruction combined with iliotibial band tendon grafting using the Arnold and Coker method and modified iliotibial band tendinosis using the Lemaire method in patients with anterior cruciate ligament rupture.

Public title
A study of three surgical methods for anterior cruciate ligament rupture.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with anterior cruciate ligament rupture who have a positive Pivot Shift test and a Pivot Shift score of 3
Exclusion criteria:
knee joint osteoarthritis simultaneous multiple ligament injury
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Shahid Beheshti University of Medical Sciences
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
19394631
Approval date
2025-02-04, 1403/11/16
Ethics committee reference number
IR.SBMU.MSP.REC.1403.633

Health conditions studied

1

Description of health condition studied
Cruciate ligament rupture
ICD-10 code
S83.5
ICD-10 code description
Sprain of cruciate ligament of knee

Primary outcomes

1

Description
knee score
Timepoint
Before the intervention and one year after ending the intervention
Method of measurement
International Knee Documentation Committee scale, Lysholm Knee Score and Knee injury and Osteoarthritis Outcome Score

2

Description
Knee function
Timepoint

Before the intervention and one year after ending the intervention

Method of measurement

International Knee Documentation Committee scale, Lysholm Knee Score and Knee injury and Osteoarthritis Outcome Score

3

Description

quality of life

Timepoint

Before the intervention and one year after ending the intervention

Method of measurement

International Knee Documentation Committee scale, Lysholm Knee Score and Knee injury and Osteoarthritis Outcome Score

Secondary outcomes

empty

Intervention groups

1

Description

Patients undergo only anterior cruciate ligament (ACL) reconstruction. The surgery is performed arthroscopically under general anesthesia. A tendon graft is used to replace the ACL and is attached to the femur and tibia with screws or standard fixation devices. No intervention is performed on the anterolateral ligament or iliotibial band in this group.

Category

Treatment - Surgery

2

Description

Patients undergo ACL reconstruction with anterolateral ligament repair using the Arnold and Coker technique. In this procedure, a portion of the iliotibial band is removed from the outer thigh and used as a graft. The surgery is performed arthroscopically and minimally invasively. The iliotibial band is guided in the appropriate direction and attached to the femur and tibia with surgical sutures and fixation devices to increase lateral knee stability in addition to ACL reconstruction.

Category

Treatment - Surgery

3

Description

Patients undergo ACL reconstruction with modified iliotibial band tendinosis using the Lemierre technique. In this technique, a portion of the iliotibial band is released from its natural location and placed in the anterolateral aspect of the knee. The surgery is performed arthroscopically under general anesthesia, and the graft is secured to the femur and tibia using sutures and fixation screws. This technique is used to enhance lateral stability and reduce knee instability in conjunction with ACL reconstruction.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-ye Tajrish Hospital

Full name of responsible person

Mehrdad Sedighi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Soroush Hoseini
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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
Maintaining patient privacy and confidentiality
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only information related to the study protocol, statistical analysis plan, and clinical study report will be made available to other researchers to guide future studies (and not publicly).
When the data will become available and for how long
After publishing the article
To whom data/document is available
Researchers, students, and professors in the field of orthopedics
Under which criteria data/document could be used
For use in future research and if the source is cited.
From where data/document is obtainable
Corresponding author Dr. Mehrdad Sedighi mehrdad_1330@yahoo.com
What processes are involved for a request to access data/document
Send a request via email to the corresponding author,

stating the reason for the request and how the data will be used.

Comments