

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name	Soroush Hosseini	Blinding description	
Name of organization / entity		Placebo	Not used
Country	Iran (Islamic Republic of)	Assignment	Parallel
Phone	+98 21 23871	Other design features	
Email address	soroush.hosseini93@gmail.com	Secondary Ids	empty
Recruitment status		Ethics committees	
Recruitment complete		1	
Funding source		Ethics committee	
Expected recruitment start date	2025-03-10, 1403/12/20	Name of ethics committee	Ethics Committee of the Faculty of Medicine, Shahid Beheshti University of Medical Sciences
Expected recruitment end date	2026-03-11, 1404/12/20	Street address	Arabi street, Velenjak
Actual recruitment start date	empty	City	Tehran
Actual recruitment end date	empty	Province	Tehran
Trial completion date	empty	Postal code	19394631
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.	Approval date	2025-02-04, 1403/11/16
Public title	A study of three surgical methods for anterior cruciate ligament rupture.	Ethics committee reference number	IR.SBMU.MSP.REC.1403.633
Purpose	Treatment	Health conditions studied	
Inclusion/Exclusion criteria		1	
Inclusion criteria:	Patients with anterior cruciate ligament rupture who have a positive Pivot Shift test and a Pivot Shift score of 3	Description of health condition studied	Cruciate ligament rupture
Exclusion criteria:	knee joint osteoarthritis simultaneous multiple ligament injury	ICD-10 code	S83.5
Age	From 18 years old to 30 years old	ICD-10 code description	Sprain of cruciate ligament of knee
Gender	Both	Primary outcomes	
Phase	N/A	1	
Groups that have been masked	No information	Description	knee score
Sample size	Target sample size: 48	Timepoint	Before the intervention and one year after ending the intervention
Randomization (investigator's opinion)	Not randomized	Method of measurement	International Knee Documentation Committee scale, Lysholm Knee Score and Knee injury and Osteoarthritis Outcome Score
Randomization description		2	
Blinding (investigator's opinion)	Not blinded	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

Street address

Valiasr street, Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934184

Phone

+98 21 25719

Email

Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Arabi street, velenjak

City

Tehran

Province

Tehran

Postal code

193954631

Phone

+98 21 23871

Email

info@sbmu.ac.ir

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

Position

Rezident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Valiasr street, Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

soroush.hosseini93@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrdad Sedighi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Vliast street, Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

mehrdad_1330@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Sabbaghzadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Valiasr street, Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dramirsabbaghzadeh@gmail.com

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