

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Name of organization / entity****Country**

Iran (Islamic Republic of)

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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

##### Street address

Valiasr street, Tajrish square

##### City

Tehran

##### Province

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##### Postal code

1989934184

##### Phone

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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

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##### Phone

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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

**Position**

Rezident

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Position**

Assistant professor

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

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**Full name of responsible person**

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**Position**

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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**