

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of kinematics and kinetic gait, after knee surgery with ACL and Anterolateral Ligament Reconstruction technique, and Lemire - tenodesis technique

#### Protocol summary

##### Study aim

The purpose of this study is to evaluate the rotation and internal pressure of the knee after surgery with ACL and Anterolateral Ligament Reconstruction technique, and Lemire tenodesis technique

##### Design

A randomized trial with two parallel group design of 20 patients which is randomized with "random allocation" software.

##### Settings and conduct

Patients with clinical sign candidates for knee surgery with ACL and anterolateral ligament reconstruction referred to the Orthopedic Clinic of Isfahan University of Medical Sciences are divided into two groups. The cruciate ligament reconstruction method will be used for The first group, and in the second group, the Lemire tenodesis technique will be used. Gait analysis will be performed for each group before and 6 month after surgery to compare kinetic and kinematic data.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study; Age range 20 to 40 years; The patient is able to walk and stand; The patient does not have any other medical problem that causes pain and prevents her from walking  
Inclusion criteria: History of knee replacement; Any lower limb fractures in the last 6 months Metabolic bone diseases

##### Intervention groups

In this study, 20 patients with unilateral anterior cruciate ligament rupture of the knee and a pivot shift test of the third degree who are candidates for anterior cruciate ligament reconstruction surgery with anterolateral ligament reconstruction will participate. One group will perform anterior cruciate ligament reconstruction with hamstring autograft and anterolateral ligament reconstruction, and the other group will perform anterior cruciate ligament reconstruction with hamstring

autograft and anterolateral ligament by Lemire tenodesis method using allograft.

##### Main outcome variables

Evaluation of kinetic and kinematic data

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180729040636N4**

Registration date: **2021-05-01, 1400/02/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-01, 1400/02/11**

Update count: **0**

##### Registration date

2021-05-01, 1400/02/11

##### Registrant information

##### Name

Hossein Akbari aghdam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3620 2085

##### Email address

akbariaghdam@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-09-23, 1400/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of kinematics and kinetic gait, after knee surgery with ACL and Anterolateral Ligament Reconstruction technique, and Lemire - tenodesis technique

**Public title**  
Comparison of kinematics and kinetic gait, after knee surgery with ACL and Anterolateral Ligament Reconstruction technique, and Lemire - tenodesis technique

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Candidates for knee surgery with ACL and Anterolateral Ligament Reconstruction admitted in the Kashani hospital. -Signing the consent form.  
**Exclusion criteria:**  
knee arthroplasty Knee surgery in the last 12 months  
Lower limb fractures in the last 6 months  
Bilateral anterior cruciate ligament injury of the knee  
Bucket-handle meniscal tear injection of intra-articular in the last 6 months  
Metabolic bone diseases osteomalacia  
Individuals with an underlying disease  
People with osteoporosis

**Age**  
From **20 years** old to **40 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **20**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients were allocated into intervention or control group using block randomization method to keep an even randomization ratio of (1:1). If the patient had inclusion criteria and did not excluded from the study according to above mentioned protocol, the random number generating software was used to determine their designated group. Numbers were between 0-9. If the number was even, the letter "A" was wrote at the top of their checklist by the examining physician, and if the number was odd, the letter "B" was used. Then, the next patient had to be assigned to the opposite group. This process repeated for the upcoming patients and continued until we reached our estimated sample size. After completing the study and before starting the data analysis process, the encrypted letters were revealed by the pharmaceutical company. The letter "A" was assigned to the intervention group and the letter "B" was

assigned to the control group.

**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 Isfahan University of Medical Sciences

##### Street address

Hezar Jerib street, Isfahan, Iran

##### City

isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-04-14, 1400/01/25

#### Ethics committee reference number

IR.MUI.MED.REC.1400.028

## Health conditions studied

### 1

#### Description of health condition studied

Anterolateral Ligament Reconstruction

#### ICD-10 code

S83.51

#### ICD-10 code description

Sprain of anterior cruciate ligament of knee

## Primary outcomes

### 1

#### Description

internal forces of knee compartments

#### Timepoint

Before the intervention and 6 months after

#### Method of measurement

motion capture system

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Reconstruction of the anterior cruciate ligament with a hamstring autograft

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group: Reconstruction of anterior cruciate ligament using hamstring autograft and anterolateral ligament by Lemir method

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Kashani Hospital

##### Full name of responsible person

Hossein Akbari Aghdam

##### Street address

Isfahan medical school, Hezarjeribstreet, Isfahan, Iran

##### City

Isfahan

##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3792 7654

##### Email

Akbariaghdam@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjooy Javanmard

##### Street address

Hezar Jerib street, Isfahan, Iran

##### City

isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 7898

##### Email

research@mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Hossein Akbari aghdam

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Nikan apartment , east allame amini ave ,ghadir park,isfahan

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##### Email

akbariaghdam@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Hossein Akbari aghdam

##### Position

Assistant professor

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Subspecialist

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## Person responsible for updating data

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Esfahan University of Medical Sciences

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Hossein Akbari aghdam

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Assistant professor

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data related to the results of data analysis and review can be shared

**When the data will become available and for how long**

3 months after the results are published in an international journal

**To whom data/document is available**

For researchers only

**Under which criteria data/document could be used**

Individuals are allowed to use the data for research purposes.

**From where data/document is obtainable**

corresponding author akbariaghdam@mui.ac.ir

**What processes are involved for a request to access data/document**

After requesting and confirming it, it will take about two weeks to send the data.

**Comments**