

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

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

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Position

Assistant professor

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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