Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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

Isfehan

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
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Person responsible for updating data

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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