Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

short term results of lateral extra articular tenodesis of the anterolateral ligament by harvesting from the hamstring tendon with modified lemaire method using the ITB fascia with out passing the graft under the lateral collateral ligament compared with classic methode in patients who underwent simultaneous reconstruction of the anterior cruciate ligament

Protocol summary

Study aim

short term results of lateral extra articular tenodesis of the anterolateral ligament by harvesting from the hamstring tendon with modified lemaire method using the ITB fascia with out passing the graft under the lateral collateral ligament compared with classic methode in patients who underwent simultaneous reconstruction of the anterior cruciate ligament

Design

Clinical trial, parallel groups, double-blind, randomized, on 100 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

Patients requiring simultaneous reconstruction of the anterior cruciate ligament and anterior lateral ligament of the knee who refer to Firoozgar Hospital in Tehran will be included in the study. Patients will be randomly divided into 2 groups based on blocks of 10. Patients, responsible for data collection, analysis and outcome assessment will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients requiring simultaneous reconstruction of the anterior cruciate ligament and anterior lateral ligament of the knee, The age range from 18 to 45 years. Exclusion criteria: Coagulation disorders, Neurological disorders.

Intervention groups

Intervention group 1: The reconstruction method of the anterior lateral ligament of the knee will be the modified Limer method. A flap 8 cm long and 1 cm wide is separated from the proximal part and then the free head of the ITB flap will be fixed with a screw without passing under the LCL, after passing through the canal, in about 40 degrees of knee flexion. Intervention group 2: After performing ACL repair surgery, they will undergo ACL reconstruction using the classic Limer method. The free head of the ITB flap will be fixed with a screw by passing under the LCL, with the knee flexed at approximately 40 degrees.

Main outcome variables

Anterior Cruciate Ligament Rupture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230518058225N11**
Registration date: **2025-04-22, 1404/02/02**
Registration timing: **prospective**

Last update: **2025-04-22, 1404/02/02**
Update count: **0**

Registration date

2025-04-22, 1404/02/02

Registrant information

Name

Anahita Sadri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-05-10, 1404/02/20
Expected recruitment end date
2025-09-11, 1404/06/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
short term results of lateral extra articular tenodesis of the anterolateral ligament by harvesting from the hamstring tendon with modified lemaire method using the ITB fascia with out passing the graft under the lateral collateral ligament compared with classic methode in patients who underwent simultaneous reconstruction of the anterior cruciate ligament

Public title
short term results of lateral extra articular tenodesis of the anterolateral ligament by harvesting from the hamstring tendon with modified lemaire method using the ITB fascia with out passing the graft under the lateral collateral ligament compared with classic methode in patients who underwent simultaneous reconstruction of the anterior cruciate ligament
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients requiring simultaneous reconstruction of the anterior cruciate ligament and anterior lateral ligament of the knee. Age 18 to 45 years
Exclusion criteria:
Patients with other or multiple ligament injuries Patients who have suffered re-trauma to the same knee Patients who underwent surgery with the allograft technique
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into 2 groups. The randomization tool will randomize the table of numbers. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 10 blocks will be formed and in each block 5 people from intervention group and 5 people will be placed in the control group. A total of 10 blocks will be considered to reach the sample size. Blocks contain numbers, numbers represent study groups. Their order will be determined by the statistician from the beginning. In order to hide the random allocation, opaque envelopes sealed with a random sequence will be used. In this method, each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. became. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will be aware that they will be randomly assigned to one of the two study groups, but will not know which method will be provided in that group. Patients will be assigned to one of two groups using a random number table. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the information based on groups 1 and 2 and will not know the type of treatment in the groups and will be kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Medicine - Iran University of Medical Sciences (Research Ethics Committee)
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-02-09, 1403/11/21
Ethics committee reference number

IR.IUMS.FMD.REC.1403.590

Health conditions studied

1

Description of health condition studied
Anterior cruciate ligament tear of the knee
ICD-10 code
S83.7
ICD-10 code description
Injury to multiple structures of knee

Primary outcomes

1

Description
Anterior Cruciate Ligament Rupture
Timepoint
Follow-up 14 days, 2 weeks, 6 weeks, 3 months and 6 months after surgery
Method of measurement
Physician's clinical examination and registration in the checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The reconstruction method of the anterior lateral ligament of the knee will be the modified Limer method, in such a way that after creating the tibial and femoral canals, an autograft is inserted for ACL reconstruction. By accessing the ITB site and identifying the anatomical origin on the femur, a flap 8 cm long and 1 cm wide is separated from the proximal part and then, after creating a transfemoral tunnel in the aforementioned location, the free head of the ITB flap will be fixed with a screw without passing under the LCL, after passing through the canal, in about 40 degrees of knee flexion.
Category
Treatment - Other

2

Description
Intervention group 2: After performing ACL repair surgery, they will undergo ACL reconstruction using the classic Limer method. An 8 cm long and 1 cm wide flap is separated from the proximal part, and after creating a transfemoral tunnel at the aforementioned location, the free head of the ITB flap will be fixed with a screw by passing under the LCL, with the knee flexed at approximately 40 degrees.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firouzgar hospital
Full name of responsible person
Farhood Abroosh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Farhood Abroosh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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