Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Evaluation of Anterior Cruciate Ligament Reconstruction(ACL) Using Isolated Techniques Versus Combined Reconstruction with the Anterior Oblique Ligament (AOL) on Rotational Stability and Clinical–Functional Outcomes: A Randomized Controlled Trial

Protocol summary

Study aim

To determine and compare the effects of two surgical techniques, including isolated anterior cruciate ligament (ACL) reconstruction and combined ACL and anterolateral ligament (AOL) reconstruction, on knee rotational stability, in patients aged 16–45 years with complete ACL tears during the 6-month postoperative period.

Design

A randomized, double-blind, parallel-group, controlled clinical trial will be conducted in 46 patients. Randomization will be performed using the Sealed Envelope website.

Settings and conduct

The target population of this study will consist of patients aged 16–45 years with a complete ACL tear presenting to Ghaem Hospital, Mashhad. At the beginning of the study, demographic characteristics, severity of rotational instability, degree of anterior knee laxity, and baseline functional scores will be recorded. Surgical interventions will be performed by experienced surgeons according to a standardized protocol. The control group will undergo isolated ACL reconstruction, whereas the intervention group will undergo ACL reconstructioncombined with AOL reconstruction. Patients will be assessed preoperatively and at 3 and 6 months after surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age 16–45 years Complete ACL tear confirmed by MRI Positive rotational instability on clinical examination Informed consent Exclusion Criteria Multiligament knee injury Previous revision ACL reconstruction Severe knee osteoarthritis History of major knee surgery

Intervention groups

intervention group:Patients undergoing anterior cruciate ligament reconstruction combined with anterior oblique ligament reconstruction control group: Patients undergoing isolated anterior cruciate ligament reconstruction

Main outcome variables

Rotational instability; Anterior knee laxity; Functional outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260425069152N1**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date

2026-09-28, 1405/07/06

Registrant information

Name
Sanaz Zabihi
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-10-07, 1405/07/15

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of Anterior Cruciate Ligament Reconstruction(ACL) Using Isolated Techniques Versus Combined Reconstruction with the Anterior Oblique Ligament (AOL) on Rotational Stability and Clinical–Functional Outcomes: A Randomized Controlled Trial

Public title

Evaluation of Anterior Cruciate Ligament Reconstruction(ACL) Using Isolated Techniques Versus Combined Reconstruction with the Anterior Oblique Ligament (AOL) on Rotational Stability and Clinica

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Complete ACL tear confirmed by MRI Positive rotational instability on physical examination Willingness to undergo surgery and participate in 6 months of follow-up

Exclusion criteria:

Multiligament injury Previous ACL reconstruction Severe osteoarthritis History of major knee surgery

Age

From **16 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization sequence will be generated using the Sealed Envelope website. Twenty blocks of three and six blocks of six will be generated. The treatment allocation for each participant will then be placed in sequentially numbered, sealed envelopes by an individual who is not involved in the research team, and the envelopes will be provided to the researchers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind trial. Participants and outcome assessors will be blinded to participants' group allocation. The randomization sequence will be generated by an individual outside the research team, and treatment allocation will be placed in sequentially numbered, sealed envelopes. Therefore, neither the investigator responsible for outcome assessment nor the participants will be aware of the assigned treatment group. Before surgery, all participants will be informed about the study protocol, and written informed consent will be obtained from all participants. Participants will then be randomly allocated to one of the two surgical groups; however, they will not be informed whether anterolateral ligament (AOL) reconstruction will be performed. The group allocation will be concealed in sequentially numbered, opaque, sealed envelopes. The relevant envelope will be opened by the surgeon immediately before surgery, without the participant being present or informed of the allocation. Information regarding the type of surgical intervention will be documented in the operative report and other surgical records in a manner that prevents access to this information by the participant. After surgery, both groups will follow the same rehabilitation protocol and identical follow-up schedule, and participants will remain unaware of their group allocation throughout the follow-up period. Outcome assessments will be performed by an independent assessor who is blinded to the participants' group allocation. Due to the nature of the surgical intervention, the surgeon and members of the treatment team directly involved in the surgical procedure cannot be blinded and will not participate in outcome assessment or statistical analysis. Statistical analysis will be performed using coded treatment groups, with the statistician blinded to the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Ethics Committee of Imam Reza (AS) Hospital

Street address

Imam Reza Hospital, Ibn Sina Street, Adjacent to Imam Reza Square, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2026-02-16, 1404/11/27

Ethics committee reference number

IR.MUMS.IRH.REC.1404.280

Health conditions studied

1

Description of health condition studied
Complete Tear of the Anterior Cruciate Ligament (ACL) of the Knee
ICD-10 code
S83.51
ICD-10 code description
Sprain of anterior cruciate ligament of knee

Primary outcomes

1

Description
Rotational Instability
Timepoint
Preoperatively, 3 Months, and 6 Months Postoperatively
Method of measurement
pivot-Shift Test and slocum test

2

Description
Anterior Knee Laxity
Timepoint
Preoperatively, 3 Months, and 6 Months Postoperatively
Method of measurement
anterior drawer test

3

Description
Functional Outcomes
Timepoint
Preoperatively, 3 Months, and 6 Months Postoperatively
Method of measurement
Knee Society Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients aged 16–45 years with a complete anterior cruciate ligament (ACL) tear confirmed by MRI and positive rotational instability on clinical examination who will undergo anterior cruciate ligament (ACL) reconstruction combined with anterior oblique ligament reconstruction.
Category
Treatment - Surgery

2

Description
Control group: Includes patients aged 16–45 years with a complete ACL tear confirmed by MRI and positive rotational instability on clinical examination who will undergo isolated anterior cruciate ligament reconstruction (ACLR).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Mohammad Hossein Ebrahimzadeh
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Ghaem Hospital, Ahmadabad Street, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Mohebati
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sanaz Zabihi
Position
researcher
Latest degree
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Other areas of specialty/work
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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
Due to confidentiality considerations and the protection of participants' information, there is no plan to share individual participant data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable