Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of quadriceps thickness in males following ACL reconstruction using hamstring vs. patellar tendon grafts

Protocol summary

Study aim
Assessment of quadriceps thickness in males following ACL reconstruction using hamstring vs. patellar tendon grafts

Design
A randomized, single-blind, parallel-group clinical trial with two intervention groups on 56 patients. Random Allocation software was used for randomization.

Settings and conduct
Study location: Biomechanics Laboratory, Faculty of Rehabilitation, Babol University of Medical Sciences Single-blind study with blinding of data analyst Determining the thickness of different parts of the quadriceps muscle using an ultrasound device .

Participants/Inclusion and exclusion criteria
Inclusion criteria 1. Men with anterior cruciate ligament injury and confirmation of complete anterior cruciate ligament tear in MRI findings 2. Confirmation of complete anterior cruciate ligament tear by an orthopedic surgeon 3. Average age 18 to 38 years 4. Surgery candidate with hamstring or patellar tendon graft Exclusion criteria 1. History of myopathy 2. History of previous knee surgery 3. History of lumbar surgery 4. History of rheumatological diseases 5. Collateral ligament or posterior cruciate ligament injuries, grade III meniscal tear, or cartilage damage 6. Lower limb injuries at least 6 months before the study

Intervention groups
Intervention Group 1: Men with ACL reconstruction with hamstring tendon graft Intervention Group 2: Men with ACL reconstruction with patellar tendon graft

Main outcome variables
Primary outcome: 1. Thickness of the vastus lateralis muscle of the affected limb 2. Thickness of the vastus medialis oblique muscle of the affected limb 3. Thickness of the vastus intermedius muscle of the affected limb 4. Thickness of the rectus femoris muscle of the affected limb Secondary outcome: 1. Thickness of the long head of the biceps femoris muscle of the affected limb

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221019056245N3**
Registration date: **2025-11-29, 1404/09/08**
Registration timing: **prospective**

Last update: **2025-11-29, 1404/09/08**
Update count: **0**

Registration date
2025-11-29, 1404/09/08

Registrant information
Name
Khodabakhsh Javanshir
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-06, 1404/09/15
Expected recruitment end date
2026-04-20, 1405/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Assessment of quadriceps thickness in males following ACL reconstruction using hamstring vs. patellar tendon grafts

Public title
Assessment of quadriceps thickness in males following ACL reconstruction using hamstring vs. patellar tendon grafts
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Men with ACL injury and confirmed complete ACL tear on MRI findings Confirmation of complete ACL tear by orthopedic surgeon Candidate for surgery with hamstring graft or patellar tendon graft
Exclusion criteria:
History of myopathy History of previous knee surgery History of lumbar surgery History of rheumatological diseases Collateral ligament or posterior cruciate ligament injuries, grade III meniscal tear, or cartilage injury Lower limb injuries at least 6 months before the study
Age
From **18 years** old to **38 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
In this parallel randomized controlled trial, given that not all patients will enter the study at the same time and that the researchers cannot predict in advance which group each patient entering the study will belong to, the block randomization method will be used to assign each patient to one of the two groups. In order to conceal the random assignment, the codes generated by the software will be placed in opaque envelopes so that it is not clear which group the next person will be placed in. In this study, eligible participating patients will be randomly assigned to one of the two control and intervention groups in a 1:1 ratio in blocks of 4 according to the block randomization protocol (generated by Random Allocation Software), after receiving informed consent, in such a way that the researcher cannot predict which intervention group the next person will be placed in. The codes will be placed in opaque envelopes, and with each new person entering, the envelope will be opened and the person's belonging to the relevant group will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this type of intervention, the patients themselves cannot be blinded. However, the data analyst will be completely unaware of which group the patients belong to in order to measure the outcomes. However, blinding the evaluator will not be possible because the operated area is specific.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Ganj afrooz St.
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Postal code
4717647745
Approval date
2025-10-05, 1404/07/13
Ethics committee reference number
IR.MUBABOL.HRI.REC.1404.129

Health conditions studied

1

Description of health condition studied
Anterior Cruciate ligament tear
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
1- Vastus lateralis thickness of affected side 2- Vastus medialis oblique thickness of affected side 3- Vastus intermedius thickness of affected side 4- Rectus femoris thickness of affected side
Timepoint
48 hours before and one week after anterior cruciate ligament reconstruction surgery
Method of measurement
Ultrasonography device

Secondary outcomes

1

Description
Long head of Biceps Femoris thickness of affected side
Timepoint
48 hours before and 1 week after anterior cruciate ligament reconstruction surgery
Method of measurement
Ultrasonography device

Intervention groups

1

Description
First Intervention group: Anterior cruciate ligament reconstruction with hamstring tendon graft
Category
Treatment - Surgery

2

Description
Second Intervention group: Anterior cruciate ligament reconstruction with patellar tendon graft
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouhani Hospital
Full name of responsible person
Khodabakhsh Javanshir
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Sponsors / Funding sources

1

Sponsor
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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
Babol 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
Babol University of Medical Sciences
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Position
Professor
Latest degree
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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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available