

# 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

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3233 6419

##### Email address

k.javanshir@mubabol.ac.ir

##### 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.

###### City

Babol

###### Province

Mazandaran

###### 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

#### Street address

Rouhani Hospital, Ganjafrooz St.,

#### City

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#### Province

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#### Postal code

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#### Phone

+98 11 3219 9592

#### Email

info@mubabol.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Mehdi Rajabnia

#### Street address

Babol University of Medical Sciences, Ganjafrooz St.,

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#### Phone

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#### Email

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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

#### Full name of responsible person

Khodabakhsh Javanshir

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiotherapy

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## Person responsible for scientific inquiries

### Contact

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#### Full name of responsible person

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**Position**

Professor

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**Person responsible for updating data**

**Contact**

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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