

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of four-strand hamstring and quadriceps autograft tendons in Arthroscopic Anterior Cruciate Ligament Reconstruction

Protocol summary

Summary

(1) Objectives: to compare the therapeutic effects of two different techniques in the treatment of ACL tear (2) Design: Randomized controlled trial. (3) Setting and conduct: Sample size of 154 patients will randomly assign into A) four-strand hamstring auto-graft tendons versus B) quadriceps auto-graft tendons in ACL Reconstruction (4) Participants: Inclusion criteria: regularly athletic cases with age 18-50 years, clinically and radiographically diagnosed as complete ACL tear . Exclusion criteria: any knee surgeries, contralateral ACL tear, other ligament injuries (except medial and lateral menisci, abnormal knee X-ray, symptomatic ankle or knee. (5) Interventions: ACL Reconstruction using A) four-strand hamstring auto-graft tendons versus B) quadriceps auto-graft tendons (6) Main outcome measures: Primary outcome is ???

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706107274N13**

Registration date: **2017-08-08, 1396/05/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-08, 1396/05/17

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

mardani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of four-strand hamstring and quadriceps autograft tendons in Arthroscopic Anterior Cruciate Ligament Reconstruction

Public title

Comparison of hamstring versus quadriceps tendons in Arthroscopic Anterior Cruciate Ligament Reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: regularly athletic cases with age 18-50 years, clinically and radiographically diagnosed as complete ACL tear . Exclusion criteria: any knee surgeries, contralateral ACL tear, other ligament injuries (except medial and lateral menisci, abnormal knee X-ray, symptomatic ankle or knee.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **154**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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, Guilan University of Medical Sciences

Street address
Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

City
Rasht

Postal code

Approval date
2017-06-03, 1396/03/13

Ethics committee reference number
IR.GUMS.REC.1396.80

Health conditions studied

1

Description of health condition studied
anterior cruciate ligament tear

ICD-10 code
S83.5

ICD-10 code description
Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

Primary outcomes

1

Description
KOOS score

Timepoint

3,6 and 12 month after surgery

Method of measurement
KOOS score standard questionnaire

2

Description
IKDC Score

Timepoint
3,6 and 12 month after surgery

Method of measurement
IKDC Score standard questionnaire

3

Description
lysholm Score

Timepoint
3,6 and 12 month after surgery

Method of measurement
lysholm Score standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The second group (reconstruction of the anterior cruciate ligament with quadriceps): After creating a 3cm incision in Antromedial site, semitendinosus and gracilis tendons will be separated with a 10mm Stripper from the muscle and four-strand graft will be used to reconstruct the anterior cruciate ligament.

Category
Treatment - Surgery

2

Description
The first group (reconstruction of the anterior cruciate ligament with hamstring): After creating a 3cm incision in Antromedial site, Hamstring tendon will be separated with a 10mm Stripper from the muscle and four-strand graft will be used to reconstruct the anterior cruciate ligament.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasht Poursina Hospital

Full name of responsible person
Mohsen Mardani Kivi MD.

Street address
Rasht,poursina Crossroads, Poursina hospital

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

shadman nemati MD, Research chancellor of Guilan university of medical science

Street address

Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

City

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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

Vice chancellor for research, Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Science

Full name of responsible person

Mohsen Mardani Kivi MD.

Position

Associated Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty