Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of anterior cruciate ligament perfusion after reconstruction with hamstring autograft in two methods of preservation or isolation of tibial junction based on dynamic contrast enhanced MRI findings of a randomized clinical trial study

Protocol summary

Study aim

Anterior cruciate ligament blood supply after reconstruction with hamstring autograft in two methods of maintaining or isolating tibial junction based on findings dynamic contrast enhanced MRI Is compared

Design

a clinical trial with a control group, with parallel groups, double-blind, approved, on 40 patients. Excel software Rand function was used for scanning.

Settings and conduct

The present study will be performed in the form of a randomized clinical trial on patients diagnosed with isolated anterior cruciate ligament injury who is a candidate for surgery referred to Shafa Yahyaian Hospital. After the approval of this plan in the ethics committee of the medical school of Iran University of Medical Sciences, and registration in the clinical trial system of the country, written informed consent will be obtained from patients who are eligible to participate in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-40 years who have suffered ACL isolation following trauma. Exclusion criteria: Knee or leg fractures Simultaneous ligament injury Meniscus damage that needs to be repaired and affects postoperative reflux Trauma to the knee or leg - Clear deformity in the knee or leg History of previous knee or leg surgery

Intervention groups

Control group: Patients with ACL tear who undergo ACL reconstruction with complete separation of the hamstring tendons from the distal and proximal. The case group, while the distal attachment of the tendon is preserved, is detached from the proximal and harvested out and reconstructed while maintaining the distal attachment.

Main outcome variables

Tibial canal widening, femoral canal widening, ACL diameter, Functional score Womac, tegnerlysholm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210520051351N1**
Registration date: **2021-06-16, 1400/03/26**
Registration timing: **prospective**

Last update: **2021-06-16, 1400/03/26**
Update count: **0**

Registration date

2021-06-16, 1400/03/26

Registrant information

Name

Mehdi Mohammadpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anterior cruciate ligament perfusion after reconstruction with hamstring autograft in two methods of preservation or isolation of tibial junction based on dynamic contrast enhanced MRI findings of a randomized clinical trial study

Public title

Comparison of anterior cruciate ligament blood flow after reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18-40 years with ACL tear following trauma

Exclusion criteria:

Knee or leg fracture Simultaneous ligament injury Meniscus damage that needs to be repaired and affects postoperative rehabilitation. Previous trauma to the knee or leg Obvious deformity in the knee or leg History of previous knee or leg surgery

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method in the present study: Simple randomization is such that the form is divided among the control and intervention groups once. Randomization unit: will be personal. Visualization layers: Using randomization layers (stratified randomization) Using random options is placed in different groups and image blocks are used for balance in groups The samples are classified according to the center of the class and then in each class with the help of software to generate a random sequence Visualization tool: Random number table How to construct a random sequence is selected one by one Explanation of Concealment of Concealment Allocation: The surgical material and the person performing the analysis are not aware of the type of intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

At the time of obtaining informed consent, patients are explained in an understandable language that they will undergo method 1 or 2 in one of these two hospitals. Random patients are operated on in one of two ways. There is no difference between the two methods in terms of preoperative and postoperative programs. There is no difference between the two methods in terms of pre- and postoperative interventions and complications. There is no difference between patients in terms of the appearance of extremity after surgery. There is no difference in preoperative and postoperative rehabilitation between the two groups. The surgeon is aware of the type of surgery, but visit the patient in the same way in both groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Mojahedin Islam St. Shafa Yahyaian Hospital

City

تهران

Province

Tehran

Postal code

1157637131

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.IUMS.REC.1399.1398

Health conditions studied

1

Description of health condition studied

Anterior cruciate ligament tear

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

Primary outcomes

1

Description

Anterior cruciate ligament vascularization rate reconstructed by preserving distal attachment

Timepoint
Measurements of vascularization were taken at 6 and 12 weeks after reconstruction
Method of measurement
With Gadolinium enhanced MRI

Secondary outcomes

1

Description
Womac and Tegner-lysholm form score
Timepoint
6 and 12 weeks after reconstruction
Method of measurement
Womac , Tegner-lysholm form

Intervention groups

1

Description
Control group: Patients with ACL tear who undergo normal ACL reconstruction surgery with complete separation of the hamstring tendons from the distal and proximal attachment. The distal and proximal hamstring tendons are detached from the lower extremity on the same side and harvested and reconstructed arthroscopically.
Category
Treatment - Surgery

2

Description
Intervention group: Patients with ACL tear who undergo ACL reconstruction surgery in a new way with complete preservation of the hamstring tendons from the distal and separation from the proximal. The hamstring tendons are preserved distally and detached from the proximal to the lower extremity on the same side, and are harvest while the distal attachment of the tendons is attached. It is then reconstructed arthroscopically.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Yahyaian Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Iran University of Medical Sciences
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Shahid Hemmat Highway between Sheikh Fazl ... Nouri and Shahid Chamran Iran University of Medical Sciences
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Grant name
Vice Chancellor for Research, Iran University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Chancellor for Research, 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

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All variables and all potential data can be shared after identifying individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
It will be available to researchers working in academic institutions, and people in industry can apply for it.
Under which criteria data/document could be used
The data can be reviewed and used to improve clinical conditions and maintain patient health and perform meta-analyzes.
From where data/document is obtainable
They can request the author's email or from the research

center or university.

What processes are involved for a request to access data/document

Apply by email or post to Iran University of Medical Sciences or Shafa Yahyaian Bone and Joint Reconstruction Research Center.

Comments