Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of Anterior Cruciate Ligament Vascularization after Reconstruction with Hamstring Autograft in two Methods of Maintaining Distal Tibial Insertion with and Without Fixation with Absorbable Interference Screw, based on the Findings of Dynamic Contrast Enhanced MRI, a Double Blind Randomized Clinical Trial Study

Protocol summary

Study aim

Comparison of Anterior Cruciate Ligament Vascularization after Reconstruction with Hamstring Autograft in two Methods of Maintaining Distal Tibial Insertion with and Without Fixation with Absorbable Interference Screw, based on the Findings of Dynamic Contrast Enhanced MRI,...

Design

Randomized clinical trial, with parallel, double-blind, randomized groups, on 40 patients. Excel software was used for randomization.

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 ...

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age over 18 years and under 50 years Patients with ACL tear that is both clinically and MRI-confirmed - Provide written consent to enter the study Criteria for not entering: ACL partial tear Deformity of varus or valgus ACL reconstruction with allograft Previous history of knee surgery History of sensitivity to contrast material Exclusion criteria: Failure to follow post-treatment protocols - Do not refer for follow-up

Intervention groups

The first group in which the distal attachment of the tendons is maintained will be used for fixation by Absorbable Iinterference Screw, which will lead to compression to the wall of the bony canal created in the tibia. the second group :This is the same in the surgical method group, but Absorbable Interference Screw And it is in this way that it is sufficient only to maintain the tibial connection of the tendons.

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: **IRCT20210520051351N2**
Registration date: **2022-04-16, 1401/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-16, 1401/01/27**
Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name
Mehdi Mohammadpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4448 2494
Email address
mehdi.668491@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-04-15, 1401/01/26
Expected recruitment end date
2023-06-20, 1402/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Anterior Cruciate Ligament Vascularization after Reconstruction with Hamstring Autograft in two Methods of Maintaining Distal Tibial Insertion with and Without Fixation with Absorbable Interference Screw, based on the Findings of Dynamic Contrast Enhanced MRI, a Double Blind Randomized Clinical Trial Study

Public title
Comparison of anterior cruciate ligament vascularization after reconstruction with maintaining distal tibia insertion and application of tibial screw
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-50 years with ACL tear following trauma Patients with ACL tear that is both clinically and MRI-confirmed Provide written consent to enter the study
Exclusion criteria:
ACL partial tear malalignment of varus or valgus ACL reconstruction with allograft Previous history of knee surgery History of sensitivity to contrast material
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method in the present study: For random assignment of patients to study groups, each eligible patient is assigned a number in the order of inclusion in the study. Randomization unit: will be individual Layers of randomization: Using stratified randomization Patients are randomly placed in different groups and random 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. Randomization tool: Random numbers according to the number of patients by Excel software The method of constructing a random sequence is selected one by one Explanation of allocation concealment: Patients do not know the type of surgery and the person performing the analysis does not know 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 one or two surgeries in one of two ways. Then a list of random numbers according to the number of patients is prepared by Excel software. This list is then divided into two parts (groups 1 and 2). Each patient will be included in the relevant group according to the number assigned to him / her upon arrival and the envelope with the patient group written on it will be delivered to the relevant doctor. Thus, the patient will not be aware of the type of intervention performed, while the physician will be aware of the type of surgical treatment adopted (double-blind). 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 the rate of complications. There is no difference between patients in terms of the appearance of organs 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 in the postoperative period he treats the patients in the same way. The surgeon is aware of the type of surgery, but he treats the patients 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

2022-03-11, 1400/12/20

Ethics committee reference number

IR.IUMS.REC.1400.1219

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 with and without tibia screw

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 and Tegner-lysholm form score

Intervention groups

1

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. And the distal connection of the tendon is fixed with a removable screw.

Category

Treatment - Surgery

2

Description

Control 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. And the distal connection of the tendon is not fixed with a removable screw.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital

Full name of responsible person

Alireza Askari

Street address

Shafa yahiehian Educational and Medical Center, Mojahedin-e-Islam St., Baharestan Square, Tehran

City

TEHRAN

Province

Tehran

Postal code

1157637131

Phone

+98 21 3354 2041

Email

mehdi.668491@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Iran University of Medical Sciences,between Sheikh Fazl ... Nouri and Shahid Chamran, Shahid Hemmat Highway

City

TEHRAN

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

adminsite@iums.ac.ir

Web page address

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?

Yes

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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Alireza Askari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Mojahedin-e-Islam Street

City

Tehran

Province

Tehran

Postal code

1157637131

Phone

+98 21 3354 2041

Email

aaskari60@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mehdi Mohammadpour

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Mojahedin-e-Islam Street

City

Tehran

Province

Tehran

Postal code

1157637131

Phone

+98 21 3354 2041

Email

mehdi.668491@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mehdi Mohammadpour

Position

Non-faculty specialist physician

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Shafa yahiehian Educational and Medical Center, Mojahedin-e-Islam St., Baharestan Square, Tehran

City

Tehran

Province

Tehran

Postal code

1157637131

Phone

+98 21 4448 2494

Fax

Email

mehdi.668491@gmail.com

Web page address

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