

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of placing the proximal 1/3 anterior cruciate ligament stump in individuals with complete anterior cruciate ligament rupture in preventing an increase in tibial tunnel diameter: a randomized controlled clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of inserting the remaining of 1/3 proximal stump of anterior cruciate ligament(ACL) in individuals with ACL tear in prevention of the tibial tunnel diameter enlargement

Design

In this phase 3 study, a parallel, double-blind, randomized controlled clinical trial of 30 patients undergoing ACL reconstruction will be evaluated. Patients were randomly divided into two groups, intervention (with residues) and control (without residues) using Random allocation software version 2 with the link (<https://random-allocation-software.software.informer.com/2.0/>)) Are allocated.

Settings and conduct

This study will be performed on 30 patients who are candidates for ACL reconstruction who refer to the Firoozgar Hospital in Tehran from the 23 October 2021 to 22 December 2022. Patients and researchers (analyzers of results) will be blind to the received surgical procedure.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age range 18-40 years 2. Patients with complete anterior cruciate ligament injury 3. Patients without a history of anterior cruciate ligament surgery 4. consent of patients to participate in the study
Exclusion criteria: 1. Patients with traumatic knee fractures 2. Joint diseases (grade 3 and 4 cartilage injury) of the knee on the same side of the operated 3. Patients with rheumatoid arthritis and arthritis and patients with axial malalignment 4. or patients with simultaneous ACL and meniscus injury who have undergone meniscus repair.

Intervention groups

Intervention group: Patients for whom 1/3 of the

proximal remnants of the anterior cruciate ligament ACL are placed in the tibial canal during surgery. control group : patients whose surgery did not use ACL residues.

Main outcome variables

Average change in tibial canal diameter; Frequency of Anterior drawer test (ADT) negative ; frequency of pivot-shift test negative

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200802048270N1**

Registration date: **2021-11-12, 1400/08/21**

Registration timing: **prospective**

Last update: **2021-11-12, 1400/08/21**

Update count: **0**

Registration date

2021-11-12, 1400/08/21

Registrant information

Name

Ahmad Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1321

Email address

azizi3981@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of placing the proximal 1/3 anterior cruciate ligament stump in individuals with complete anterior cruciate ligament rupture in preventing an increase in tibial tunnel diameter: a randomized controlled clinical trial

Public title

observation of prevention of tibia tunneling

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 40 years old complete anterior cruciate ligament
Consent to participate in the study

Exclusion criteria:

history of previous surgery due to anterior cruciate
ligament injury History of surgery on other lower limbs

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: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random chain construction of two groups of 15 A (intervention group) and B (control group) using Excel software will be used. In a column of 15 letters A and 15 letters B and in the adjacent column with the Rand command, make 30 random numbers. Arrange both columns in random order from large to small. The sequence of letters A and B will be the random sequence used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and researchers analyzing the results will be blind to the surgical procedure.

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

Tehran Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2021-03-06, 1399/12/16

Ethics committee reference number

IR.IUMS.FMD.REC.1399.787

Health conditions studied**1****Description of health condition studied**

disruption of anterior cruciate ligament of knee

ICD-10 code

M23.61

ICD-10 code description

Other spontaneous disruption of anterior cruciate
ligament of knee

Primary outcomes**1****Description**

Tibial canal diameter change 1

Timepoint

The diameter of the tibial tunnel is measured during the operation and 12 months after the operation.

Method of measurement

The diameter of the tibial tunnel is measured during surgery and 12 months after surgery using a CT scan by an orthopedic surgeon.

Secondary outcomes**1****Description**

Frequency of anterior sliding test negative

Timepoint

12 months after surgery

Method of measurement

Clinical examinations

2

Description

Frequency of negative pivot-shift test

Timepoint

12 months after surgery

Method of measurement

Clinical examinations

3

Description

Lysholm scale score

Timepoint

12 months after surgery

Method of measurement

Lysholm scale questionnaire

4

Description

lkdc scale score

Timepoint

12 months after surgery

Method of measurement

lkdc scale questionnaire

5

Description

Frequency of Lachman test negative

Timepoint

12 months after surgery

Method of measurement

Clinical examinations

Intervention groups

1

Description

Patients who during surgery, 1/3 of the proximal remnants of the anterior cruciate ligament (ACL) stump remain in the tibial canal.

Category

Treatment - Surgery

2

Description

Control group: Patients without proximal remnants of the anterior cruciate ligament (ACL) stump in the tibial canal

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr. Hamidreza Yazdi

Street address

Valiasr Square, Karim Khan Zand St., Beh Afarin St., Tehran

City

Tehran

Province

Tehran

Postal code

4871115937

Phone

+98 21 8214 1000

Email

dr.yazdi88@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Email

research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Ahmad Azizi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Valiasr Square, Karim Khan Zand St., Beh Afarin St. Tehran
City
Tehran
Province
Tehran
Postal code
4871115937
Phone
+98 21 8214 1000
Email
azizi3981@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hamidreza Yazdi
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Valiasr Square, Karim Khan Zand St., Beh Afarin St, Tehran
City
Tehran
Province
Tehran
Postal code
4871115937
Phone
+98 21 8214 1000
Email
dr.yazdi88@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ahmad Azizi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work

Orthopedics
Street address
Valiasr Square, Karim Khan Zand St., Beh Afarin St, Tehran
City
Tehran
Province
Tehran
Postal code
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Phone
+98 21 8214 1000
Email
azizi3981@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Unidentifiable personal data of participants will be shared upon request upon completion of the study. The protocol of surgery and study will be provided to the researchers in the form of a report after the end of the study. Statistical analysis of the data of this study will be shared in the form of a report after the end of the study. Informed design consent form, study clinical reports and codes used in the analysis will be shared in the form of a report at the end of the study. Part of the data, such as information about the main outcome or the like, will be published collectively without identifying individuals in the form of an article.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

researchers

Under which criteria data/document could be used

Use to enhance knowledge and researchers without permission to manipulate documents

From where data/document is obtainable

Firoozgar Hospital

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

Send a written request and then review and if the request is approved, the documents will be delivered. (Maximum one month)

Comments