Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

IIn 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

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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
۱۴۴۹۶۱۴۵۳۵
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
Ikdc scale score
Timepoint
12 months after surgery
Method of measurement
Ikdc 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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Person responsible for scientific inquiries

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Position
professor

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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