

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison of clinical results using hamstring versus quadriceps tendon graft and versus bone-patella tendon in anterior cruciate ligament reconstruction , a randomized clinical trial

#### Protocol summary

##### Study aim

In this plan, important results are obtained that show which graft is better for the reconstruction of the ACL.

##### Design

This research is a prospective interventional study of the type of randomized controlled clinical trial with three arms (3-arm RCT) which aims to compare the clinical results of anterior cruciate ligament reconstruction with hamstring tendon, quadriceps tendon and patella tendon. The protocol of this study will be based on SPIRIT (Standard Protocol Items: Recommendations for Intervention Trials) guidelines. This study is a randomized study with 3 arms (3 treatment groups) in a parallel manner, in which 63 participants who meet the study entry and exit conditions are selected and are followed up for 12 months after the intervention.

##### Settings and conduct

Army employees and soldiers who entered the study based on the entry and exit criteria, their demographic information is obtained by interviewing and completing a questionnaire, then after randomization, random allocation, and concealment, they are randomly divided into 3 groups, and each group undergoes a type of operation. Surgery is done by a surgeon and with a fixation method, and immediately after the operation, as well as the follow-up periods of 3, 6, and 12 months, they are examined and asked about function, pain level, and clinical examinations of ligament laxity, and at the end of the patients' information it is subjected to statistical analysis by SPSS program.

##### Participants/Inclusion and exclusion criteria

Patients who undergo ACL resection surgery, Age above 18 years, BMI  $\leq$  35, ACL tear

##### Intervention groups

Patients who undergo ACL resection surgery from 1400 to 1402.

##### Main outcome variables

Need for re-surgery, Lachman test status, pivot shift test status, anterior traction test status, score, anterior knee pain, knee range of motion, satisfaction level, time to return to normal activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230716058805N1**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

##### Registration date

2023-07-31, 1402/05/09

##### Registrant information

##### Name

Nima Hoseinizare

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2236 9615

##### Email address

nimazr70@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-21, 1400/01/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of clinical results using hamstring versus quadriceps tendon graft and versus bone-patella tendon in anterior cruciate ligament reconstruction , a randomized clinical trial

**Public title**  
Comparison of different methods of knee anterior cruciate ligament surgery

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

1. Patients who undergo anterior cruciate ligament resection surgery
2. Over 18 years of age
3. BMI  $\leq$  35
4. Willingness and ability to prepare a written consent form
5. Willingness and ability to perform subjective evaluations and have the ability to understand written questionnaires
6. Present May he not take any medicine that changes knee symptoms throughout the study until the end.
7. Willingness and ability to agree to the conditions related to the study and procedures and visits.

**Exclusion criteria:**

1. Injuries associated with ACL such as torn meniscus or posterior cruciate ligament
2. Follow-up of patients under 12 months
3. Patients who had complications such as thrombosis or embolism during or immediately after surgery
4. Patients who do not come for follow-up
5. Diseases High-risk medical condition such as kidney, liver and heart failure
6. History of addiction
7. A history of any surgery related to the knee
8. Contraindications for imaging and MRI
9. Mental disorders
10. Progressive neurological disorders
11. Having pain in another place that causes disturbance in the assessment of shoulder pain

**Age**  
No age limit

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **63**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Participants will be randomly divided into three groups 1:1:1. Each patient who enters the study will be assigned a unique number. Using the method of balanced consecutive blocks (Permuted Balanced Block Randomization) and the command of random numbers in Microsoft Office Excel 365 software, the table of random assignment of each patient to one of three different

surgical groups is prepared. Patients based on their unique number specified in the patient report form; They are divided into one of three groups. Concealment: The random numbers generated for assigning referring patients to different treatment groups will be hidden from the opinion and information of the project manager and collaborators until the end of the study, and will be revealed after data analysis. In order to hide the sequence of generated random numbers, they are assigned to different treatments through pre-determined codes, and the clinical colleagues do not have any knowledge of the defined assigned code when prescribing. The orthopedic surgeon will be informed of the patient's assigned group on the day of the operation.

**Blinding (investigator's opinion)**

Not 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 of Army Medical Sciences University

**Street address**

NO. 7, West 5th AVE, Morvarid BLVD, Saadat abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1998745363

**Approval date**

2022-08-21, 1401/05/30

**Ethics committee reference number**

IR.AJAUMS.REC.1401.075

**Health conditions studied**

**1**

**Description of health condition studied**

anterior cruciate ligament tear

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Army employees and soldiers who have ruptured the anterior cruciate ligament, their demographic information is obtained by interviewing and completing a questionnaire, then after randomization, random allocation, and concealment, they are randomly divided into 3 groups, and each group undergoes a type of surgery by They are placed by a surgeon and with a fixation method, and immediately after the operation, as well as the follow-up periods of 3, 6, and 12 months, they are examined and asked about function (Lee Scholem questionnaire), pain level, and clinical examinations of ligament laxity, and at the end, the patient information is provided by the program. SPSS is subjected to statistical analysis.

#### **Timepoint**

Immediately after the operation, as well as the follow-up periods of 3, 6, and 12 months

#### **Method of measurement**

They are examined and questioned in terms of function (Lee Scholem questionnaire), pain level and clinical examinations for ligament laxity.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: First: 21 patients undergo anterior cruciate ligament surgery with patellar tendon.

#### **Category**

Treatment - Surgery

### **2**

#### **Description**

Intervention group: The second group: 21 patients undergo hamstring surgery.

#### **Category**

Treatment - Surgery

### **3**

#### **Description**

Intervention group: Third: 21 patients undergo anterior cruciate ligament surgery with quadriceps tendon.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Army hospitals (501) in Tehran

##### **Full name of responsible person**

Nima Hoseinizare

##### **Street address**

No 7, 5th West AVE, Morvarid Street, Saadat abad

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

+98 21 2236 9615

##### **Email**

nimazr70@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Artesh University of Medical Sciences

##### **Full name of responsible person**

Doctor Heidari

##### **Street address**

Shahid Etemadzadeh St, West Fatemi St., Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1411718541

##### **Phone**

+98 21 8609 6350

##### **Email**

nimazr70@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Artesh 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**

Artesh University of Medical Sciences

##### **Full name of responsible person**

Nima hoseinizare

##### **Position**

Specialist

##### **Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

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**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Nima Hoseinizare

**Position**

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**Latest degree**

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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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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