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 ≤ 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 ≤ 35 Willingness and ability to prepare a written consent form 4. Willingness and ability to perform subjective evaluations and have the ability to understand written questionnaires 5, Suffering from rupture 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

Tehran

Province

Tehran

Postal code

1998745363

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
Street address
No. 7, 5th West AVE, Morvarid ST, Saadat abad
City
Tehran
Province
Tehran
Postal code
1998745363
Phone
+98 21 2236 9615
Email
nimazr70@gmail.com

Person responsible for scientific 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
Street address
No.7, 5th West AVE, Morvarid ST, Saadat abad
City
Tehran
Province
Tehran
Postal code
1998745363
Phone
+98 21 2236 9615
Email
nimazr70@gmail.com

Person responsible for updating data

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
Street address
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Email
nimazr70@gmail.com

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