

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of four weeks of selected rehabilitation exercises before surgery with the emphasis on core stability exercises on knee functional indexes after surgery in athletes with anterior cruciate ligament rupture: clinical trial

Protocol summary

Study aim

The effect of 4 weeks of selected rehabilitation exercises before surgery with the emphasis on core stability exercises on knee functional indexes after surgery in athletes with anterior cruciate ligament rupture

Design

This study is in the form of pre-test and post-test, according to the entry criteria, 40 people will be divided into two groups. Both groups will be pre-tested before surgery, and post-test will be taken from them 4 weeks after surgery

Settings and conduct

Evaluation of the range of motion and TKE using a goniometer, fear of movement using Tampa questionnaire, pain level using the vas questionnaire, and knee function using the IKDC questionnaire these functional evaluations will be done in the IFSM

Participants/Inclusion and exclusion criteria

The inclusion criteria of this research are: 1. Fear of movement between 18 and above 27 according to Tampa fear of movement questionnaire 2. The time from injury to surgery is maximum 3 months 3. Age range between 18 and 35 years 4. Rupture of the anterior cruciate ligament on one side 5. Not participating in any sports activities after tearing the anterior cruciate ligament The exclusion criteria of this study are: 1. Not using the same graft for each of the studied subjects 2. Intensification of injury, pain and swelling during each of the stages of the research 3. Lack of regular participation in each of the training sessions during each of the stages of the research 4. Dissatisfaction of any of the subjects during the research stages

Intervention groups

At this stage, the subjects will be randomly divided into experimental and control groups. The people of the experimental group will carry out the rehabilitation

training program for 4 weeks and 3 days a week, and the control group will have their routine activities

Main outcome variables

Range of motion, pain, fear of movement, terminal knee extension, knee function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231006059636N1**

Registration date: **2023-10-17, 1402/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-17, 1402/07/25**

Update count: **0**

Registration date

2023-10-17, 1402/07/25

Registrant information

Name

Negar Iranmanesh

Name of organization / entity

Faculty of Physical Education and Sport Sciences, Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-14, 1402/07/22

Expected recruitment end date

2024-01-12, 1402/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of four weeks of selected rehabilitation exercises before surgery with the emphasis on core stability exercises on knee functional indexes after surgery in athletes with anterior cruciate ligament rupture: clinical trial

Public title

The effect of four weeks of selected rehabilitation exercises before surgery with the emphasis on core stability exercises on knee functional indexes after surgery in athletes with anterior cruciate ligament rupture: clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Fear of movement between 18 and above 27 according to the Tampa fear of movement questionnaire The time from injury to surgery is a maximum of 3 months Age range between 18 and 35 years One-sided anterior cruciate ligament rupture Not participating in any sports activity after tearing the anterior cruciate ligament

Exclusion criteria:

Not using the same graft for each of the studied subjects Intensification of injury, pain and swelling during each of the stages of research Lack of regular participation in any of the training sessions during any of the stages of the research Dissatisfaction of any of the subjects during the research process

Age

From **17 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random - lottery (in this method, the researcher gives a code or a special number to each member of the society. Then he writes down the number of each of them on a piece of paper, then he pours them into a container and shakes them. Then the papers are separated one by one. take them out, write down their numbers and divide them into experimental and control groups

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**

The Ethics Committee of the Research Institute of Physical Education and Sports Sciences

Street address

No.3, 5th Alley, Miremad St., Ostad Motahari St., Tehran

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2023-10-13, 1402/07/21

Ethics committee reference number

SSRI.REC-2305-2220

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

Rupture of anterior cruciate ligament

ICD-10 code

S83.5

ICD-10 code description

Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

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

Range of motion

Timepoint

4 weeks before ACL reconstruction and 4 weeks after surgery

Method of measurement

Goniometer

2**Description**

Terminal knee extension

Timepoint

4 weeks before ACL reconstruction and 4 weeks after surgery

Method of measurement

Goniometer

3

Description

Fear of movement

Timepoint

4 weeks before ACL reconstruction and 4 weeks after surgery

Method of measurement

Tampa questionnaire

4

Description

Pain

Timepoint

4 weeks before ACL reconstruction and 4 weeks after surgery

Method of measurement

Visual Analogue scale

5

Description

Knee joint function

Timepoint

4 weeks before ACL reconstruction and 4 weeks after surgery

Method of measurement

International Knee Documentation Committee questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group, after reviewing the records and meeting the entry criteria, all of whom have torn the anterior cruciate ligament and are athletes, 20 people will be selected by the surgeon to implement an exercise program to strengthen the muscles of the central region before the operation, and then with written consent will be obtained from these people, then for 4 weeks and 3 sessions a week, all these athletes will receive their exercises under the direct supervision of a physiotherapist, finally, immediately before the operation, in order to assess the level of pain, The range of motion, terminal knee extension, function of the knee joint and fear of movement of these people will be examined and post-tested, then the experimental group will undergo anterior cruciate ligament reconstruction, and 4 weeks after the reconstruction of

the anterior cruciate ligament they will be tested again. The test will be taken and will be compared with the control group.

Category

Rehabilitation

2

Description

Control group: after examining the records and evaluating the patients with anterior cruciate ligament injury, 20 patients were invited by the surgeon to obtain informed written consent from the subjects, and in these 4 weeks, the control group continued their routine activities. given and before the surgery under the direct supervision of the physiotherapist immediately before the operation, the amount of pain, the range of motion, terminal knee extension, the function of the knee joint and the fear of movement of these people will be examined and pre-tested, then the control group will undergo ligament reconstruction. Anterior cruciate ligaments will be placed and 4 weeks after the reconstruction of the anterior cruciate ligament, they will be tested again and will be compared with the experimental group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Medicine Federation of Islamic Republic of Iran

Full name of responsible person

Farshad Ghazalian

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Sport Medicine Federation, No.17, Varzandeh St.,Tehran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Mostafa Zareei

Street address

Shahid Beheshti University, Shahid Shahriari
Square, Evin, Tehran, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University

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**

Shahid Beheshti University

Full name of responsible person

Amirhosein Barati

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The Information about the subjects is personal and will
not be shared with others

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
No - There is not 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 Information except the subjects` personal
Information.

When the data will become available and for how long
Six month after the results are published
To whom data/document is available
All researchers
Under which criteria data/document could be used
The use of research result is unimpeded by acquiring the
source
From where data/document is obtainable
n.iranmanesh@mail.sbu.ac.ir
What processes are involved for a request to access data/document
At least two working days
Comments