

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation and comparison of postoperative results of anterior cruciate ligament (ACL) double fixation in Tibia by screw and staple with fixation by screwing alone

Protocol summary

Study aim

Evaluation and comparison of postoperative results of anterior cruciate ligament (ACL) double fixation in Tibia by screw and staple with fixation by screwing alone

Design

Randomized Clinical Trial, without Blinding with parallel groups.

Settings and conduct

This clinical trial will be carried out in 1398. 30 patients who will be referred to Kashani and Alzahra hospitals who have anterior cruciate ligament rupture and require transplant reconstruction surgery and will be eligible for inclusion criteria will be selected. In this study, blinding will not occur. Patients will be divided into two groups. The first group consists of patients undergoing ACL rehabilitation using screw and staple fixation, and the second group consisting of patients undergoing ACL fixation with a screw (patients are under restoration arthroscopy) after surgery, patients undergo physical therapy three times a week until the 6th week during the first week.

Participants/Inclusion and exclusion criteria

1. Age between 18 to 50 years 2. Patients with anterior cruciate ligament rupture Non-inclusion criteria: 1. If the patient will be in need for knee osteotomy 2. If several other ligaments, including the other knee ligaments, will be involved 3. Do not suffer from autoimmune diseases or immunocompromised conditions

Intervention groups

The first group consists of patients undergoing acl rehabilitation with the use of screw and staple fixation and the second group consisting of patients undergoing acl rehabilitation with the use of fixation with screw (patients undergo surgery under arthroscopy), after surgery In the first week, both groups will undergo physiotherapy three times a week until the 6th week

Main outcome variables

Return to daily activities, the degree to which patients will be satisfied with the function of the knee, and the extent to which the surgery will reduce their expected activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N28**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **prospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of postoperative results of anterior cruciate ligament (ACL) double fixation in Tibia by screw and staple with fixation by screwing alone

Public title

Evaluation and comparison of postoperative results of anterior cruciate ligament (ACL) double fixation in Tibia by screw and staple with fixation by screwing alone

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 50 years Patients with anterior cruciate ligament rupture Consciousness of Patients to Participate in the Study The first time that the knees are in trouble

Exclusion criteria:

Need of osteotomy If several other ligaments, including the other knee ligaments, are involved Do not suffer from autoimmune diseases or immunocompromised conditions

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Randomization block, randomization unit: Individual, Random layer: not done Randomization, tool: Random sequence generation software (Excel), How to create random sequence: Using random blocks, each block contains 4 people And assign a number from 1 to 6 to each block

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Azadi Square, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-10-08, 1396/07/16

Ethics committee reference number

IR.MUI.MED.REC.1397.074

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

Sprain of unspecified cruciate ligament of knee

ICD-10 code

S83.50

ICD-10 code description

Sprain of unspecified cruciate ligament of knee

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

Return to daily activities

Timepoint

6 weeks after surgery

Method of measurement

International Knee Documentation Committee Questionnaire (IKDC)

2**Description**

Patient satisfaction from knee function

Timepoint

6 weeks after surgery

Method of measurement

International Knee Documentation Committee Questionnaire (IKDC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group first: Includes patients who are undergoing ACL rebuilding using bolted and staple fixation

Category

Treatment - Devices

2

Description

Intervention group second: Including patients undergoing ACL fixation with a screw (patients undergo surgery under arthroscopy)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr Hamid Moosavi

Street address

Alzahra hospital, Sofe street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81747-86398

Phone

+98 31 1668 5555

Email

hos.lolagar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences, Hezar jareeb street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3060

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Hamid Moosavi

Position

Associated Proffessor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Alzahra Hospital, Sofe Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 1625 5555

Email

h_mousavi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Hamid Moosavi

Position

Associated Proffessor

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h_mousavi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Hamid Moosavi

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Alzahra Hospital, Sofe Street, Isfahan, Iran

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Province

Isfahan

Postal code

8174675731

Phone

+98 31 1625 5555

Email

h_mousavi@med.mui.ac.ir

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

Yes - There is a plan to make this available

Title and more details about the data/document

Whole data will be shared

When the data will become available and for how long

immediately after publishing manuscript

To whom data/document is available

for all who need this data.

Under which criteria data/document could be used

Use of data is allowed for all individuals and for all purposes.

From where data/document is obtainable

Receive article from the corresponding author of the article.

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

Email To corresponding author of the article.

Comments