

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparative results of bioabsorbable screw and endobutton femoral fixation of bone patellar tendon bone graft for Anterior cruciate ligament reconstruction

Protocol summary

Study aim

Evaluation results of bioabsorbable screw and endobutton femoral fixation of bone patellar tendon bone graft for Anterior cruciate ligament reconstruction

Design

This study is clinical trial and double blind. 42 patients candidate Anterior cruciate ligament reconstruction in Valiasr hospital and Amiralmomenin hospital will inter this study. We will divide patients in 2 groups by simple randomization. Groups are parallel.

Settings and conduct

42 patients candidate Anterior cruciate ligament reconstruction in Valiasr hospital and Amiralmomenin hospital in Arak will inter this study. This study is double blind. Outcome assessor and analyzer not aware from grouping. Codes of group are available to analyzer and outcome assessor. We record physical problems of the knee, objective and subjective surgical outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Over 15 years old, candidate for surgical reconstruction of cruciate ligament, anterior cruciate ligament rupture that has no history of previous surgery on the knee, the knee of the leg is correct, anterior cruciate ligament rupture is confirmed by a clinical examination and MRI Exclusion criteria: Dissatisfaction, patients who have suffered from knee surgery, psychiatric patients or severely addicted patients

Intervention groups

Intervention group 1: We will do surgery patients with endobutton femoral fixation. Intervention group 2: We will do surgery patients with bioabsorbable screw femoral fixation.

Main outcome variables

Physical problems of the knee, objective and subjective surgical outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190508043524N1**

Registration date: **2019-08-11, 1398/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-11, 1398/05/20**

Update count: **0**

Registration date

2019-08-11, 1398/05/20

Registrant information

Name

Arsham Jangmiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

arshamjangmiri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-16, 1397/09/25

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative results of bioabsorbable screw and endobutton femoral fixation of bone patellar tendon bone graft for Anterior cruciate ligament reconstruction

Public title

Comparative results of bioabsorbable screw and endobutton femoral fixation of bone patellar tendon bone graft for Anterior cruciate ligament reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 15 years old Candidate for surgical reconstruction of cruciate ligament Anterior cruciate ligament rupture that has no history of previous surgery on the knee The knee of the leg is correct. Anterior cruciate ligament rupture is confirmed by a clinical examination and MRI

Exclusion criteria:

Dissatisfaction Patients who have suffered from knee surgery. Psychiatric patients or severely addicted patients

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, A

City

Arak

Province

Markazi

Postal code

38149578558

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.ARAKMU.REC.1397.211

Health conditions studied

1

Description of health condition studied

Anterior cruciate ligament reconstruction

ICD-10 code

M23.61

ICD-10 code description

Other spontaneous disruption of anterior cruciate ligament of knee

Primary outcomes

1

Description

Physical problems of the knee

Timepoint

Before surgery and 12 months after surgery

Method of measurement

lysholm score

2

Description

objective surgical outcome

Timepoint

Before surgery and 12 months after surgery

Method of measurement

KDLC score

3

Description

Subjective surgical outcome

Timepoint

Before surgery and 12 months after surgery
Method of measurement
KDLC score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:We will do surgery patients with endobutton femoral fixation .

Category

Treatment - Surgery

2

Description

Intervention group 2:We will do surgery patients with bioabsorbable screw femoral fixation .

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Hosseinali Hadi

Street address

Valiasr hospital, Valiasr squire, Arak

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38149578558

Phone

+98 86 3222 2003

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hadi@arakmu.ac.ir

2

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Hosseinali Hadi

Street address

Amiralmomenin hospital, Sardasht

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hadi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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3848176941

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Email

arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hosseinali Hadi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Shahid Shirodi street, Valiasr square, Valiasr hospital

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr Hosseinali Hadi

Position

Assistant professor

Latest degree

Subspecialist

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

Arsham Jangmiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Fax**Email**

arshamjangmiri@yahoo.com

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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Hadi Valiasr Hospital, Valiasr square, Shahid Shirodi street 3814957558

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

Contact With Dr Hadi at the following email address.

Hadi@arakmu.ac.ir

Comments