

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison results of anterior cruciate ligament (ACL) reconstruction using 4-strand semi tendinosus - gracilis and the semitendinosus tendon alone in patients undergoing ACL surgery

Protocol summary

Summary

In this study we compare two methods of anterior cruciate ligament (ACL) reconstruction surgery in order to determine the best approach. This is a single blind clinical trial on 70 patients with anterior cruciate ligament (ACL) injuries. Inclusion criteria are: ACL injuries within last five months, normal opposite knee. Exclusion criteria are: previous knee surgery, associated ligament injury, abnormal radiographies. The patients will be divided into two groups. The surgical condition for all of them is identical except using of one or two tendons. All operations will be done by a same team of surgery. In one group, cruciate ligament reconstruction is performed by using 4-strand semi tendinosus - gracilis and in another group, the semitendinosus tendon alone. Three months and one year after surgery the patient will be visited by two specialists separately, and based on clinical findings, the questionnaire will be filled and the knee will be examined by KT2000 Test. Differences in knee extension are verified by lateral knee radiography in full extension. Lachman test, anterior drawer test and pivot shift test is performed in both legs, and the difference between the two knees is defined and classified by Lysholm and Koos-IKDC directories. Forty-five days after surgery, control radiography is taken. One year later, another specialist who is blind to the study, performs physical examinations consist of isometric and isokinetic hamstring strength (torque peak angle) and knee flexion angle in standing position. Finally obtained data collected and mean scores of every section will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105166497N1**

Registration date: **2013-04-15, 1392/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-04-15, 1392/01/26

Registrant information

Name

Mahmood Karimi Mobarakeh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1272 2988

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2012-08-24, 1391/06/03

Expected recruitment end date

2013-02-21, 1391/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison results of anterior cruciate ligament (ACL)

reconstruction using 4-strand semi tendinosus - gracilis and the semitendinosus tendon alone in patients undergoing ACL surgery

Public title

Comparison results of two methods of anterior cruciate ligament reconstruction surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: ACL (anterior cruciate ligament) injuries within last five months, normal opposite knee, feasibility of completing specific rehabilitation program, willingness to follow up. Exclusion criteria are: previous knee surgery (Arthroscopy or Meniscus surgery), associated ligament injury, grade 3 or 4 chondral damage, abnormal radiographies.

Age

From **16 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomizing will be done by computer and the type of group is in an envelope. Just after removing tendon, the envelope will be opened and decision will be made according to it. The patients will sign informed consent but they are blind to the method of surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman Medical University

Street address

Jomhoori boulevard

City

Kerman

Postal code

Approval date

2012-03-18, 1390/12/28

Ethics committee reference number

k/90/420

Health conditions studied

1

Description of health condition studied

ACL

ICD-10 code

S83.5

ICD-10 code description

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

Primary outcomes

1

Description

knee stability

Timepoint

three months and one year after operation

Method of measurement

by KT2000

Secondary outcomes

1

Description

IKDC (international knee demographic)

Timepoint

three and one year after operation

Method of measurement

IKDC questionnaire

2

Description

KOOS(knee injury and osteoarthritis outcome score)

Timepoint

three and one year after operation

Method of measurement

KOOS questionnaire

3

Description

Passive flexion of knee

Timepoint

three and one year after operation

Method of measurement

physical test

4

Description

Lysholm score

Timepoint

three and one year after operation

Method of measurement

Lysholm questionnaire

5

Description

Isometric hamstring strength of knee

Timepoint

one year after operation

Method of measurement

Maximum peak torque deficit of normal limp

6

Description

Isokinetic hamstring strength of knee

Timepoint

one year after operation

Method of measurement

Maximum peak torque deficit of normal limp

Intervention groups

1

Description

Intervention: cruciate ligament reconstruction by using 4-strand semi tendinuous - gracilis

Category

Treatment - Surgery

2

Description

control: cruciate ligament reconstruction by semi tendinuous

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Bahonar Hospital of Kerman

Full name of responsible person
Ahmad Mortazavi

Street address
Baghmelli Square

City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person
Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

City

Kerman

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, Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Ahmad Mortazavi

Position
Resident of orthopedics

Other areas of specialty/work

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Kerman University of Medical Sciences

Full name of responsible person

Ahmad Mortazavi

Position

Resident of orthopedics

Other areas of specialty/work**Street address**

Bahonar Hospital, Baghmelli Square

City

Kerman

Postal code**Phone****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty