Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 tendinousus - 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

Email address

m_karimi@kmu.ac.ir

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 tendinousus - gracilis
Category
Treatment - Surgery

2

Description
control: cruciate ligament reconstruction by semi tendinousus
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
Street address
Bahonar Hospital, Baghmelli Square
City
Kerman
Postal code
Phone
+98 34 1226 3815
Fax
Email
dmortazavi_a59@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mahmood Karimi Mobarakeh
Position
orthopedist
Other areas of specialty/work
Street address
Bahonar Hospital, Baghmelli Square
City
Kerman
Postal code

Phone
+98 34 1223 5011
Fax
Email
drkarimi_m@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Bahonar Hospital, Baghmelli Square
City
Kerman
Postal code
Phone
+98 34 1223 5011
Fax
Email
dmortazavi_a59@yahoo.com
Web page address

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