

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

###### 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 tendinuousus - gracilis

#### Category

Treatment - Surgery

### 2

#### Description

control: cruciate ligament reconstruction by semi tendinuousus

#### 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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## Person responsible for scientific inquiries

#### Contact

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**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*