

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Randomized clinical trial of the result of transtibial Trans-Fix and transportal Trans-Fix femoral fixation surgery methods in anterior cruciate ligament reconstruction

Protocol summary

Summary

The use of Transfix technique is well accepted when performing anterior cruciate ligament reconstruction. We intended to compare the clinical results of transtibial Transfix ACL reconstruction with transportal TransFix method. :One hundred and eighty active young patients with anterior cruciate ligament injury will randomize into either transtibial TransFix (Arthrex, Naples, FL, USA) or transportal TransFix femoral fixation. patients with infection, previous surgery, age over 40 years old, bilateral injuries and who had other ligament injuries that need reconstruction. After one year patients will be clinically evaluated for results using history and physical examination. For objective measurements Rolimeter will be used to evaluate the laxity. Positions of tunnels will be also evaluated in postoperative AP radiography using Sommer technique. We use Tegner activity level score and Lysholm scaling score to evaluate the clinical results. At the end results will be analyzed using statistical methods

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102145276N2**

Registration date: **2011-05-17, 1390/02/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-17, 1390/02/27

Registrant information

Name

Fardin Mirzatolooei

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1337 3606

Email address

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2007-12-31, 1386/10/10

Expected recruitment end date

2009-11-22, 1388/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of the result of transtibial Trans-Fix and transportal Trans-Fix femoral fixation surgery methods in anterior cruciate ligament reconstruction

Public title

Comparison between two different surgical treatment methods in anterior cruciate ligament reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Symptomatic young active patients with ACL tear Exclusion criteria: Patients with infection; previous surgery; age over 40 years old; bilateral injuries and concomitant ligamentous injuries needs surgery.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **223**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Orthopedic Ward Research Committee

Street address

Orthopedic Ward Office

City

Urmia

Postal code**Approval date**

2007-12-17, 1386/09/26

Ethics committee reference number

1

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

Anterior cruciate ligament surgery

ICD-10 code

S83.5

ICD-10 code description

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

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

Clinical results of anterior cruciate reconstruction

Timepoint

Before and one year after intervention

Method of measurement

Lysholm score

2**Description**

Level of sport activity

Timepoint

Before and one year after intervention

Method of measurement

Tagner activity level score

3**Description**

Ligament laxity

Timepoint

Before and one year after intervention

Method of measurement

Rolimeter

Secondary outcomes**1****Description**

Complications of surgery

Timepoint

During operation and also one year later

Method of measurement

Registration of complications in operation chart and opd charts

Intervention groups**1****Description**

Control group: Transtibial method, this is the current method through which every surgeon reconstruct anterior cruciate ligament. In this method femoral tunnel reconstruct through tibial tunnel

Category

Treatment - Surgery

2**Description**

Intervention group: Transportal method; This is the new method we want to know its efficacy comparing to the transtibial method. In this method femoral tunnel is created through inferomedial portal

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center**

Name of recruitment center

Emam Khomeini hospital of Urmia University of
Medical Sciences

Full name of responsible person

Fardin Mirzatolooei

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no34, 16 meter, shahidAsghari ave, Emamat boulevard

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Urmia

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Urmia University of Medical Sciences

Full name of responsible person

Dr. Mohamad Motazaker

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Jahad square, research council

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Urmia

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Urmia 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**

Urmia University of Medical Sciences

Full name of responsible person

Fardin Mirzatolooei

Position

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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

