Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Tagner 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

fm.tolooei@umsu.ac.ir

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 Commitee
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
Street address
no34, 16 meter, shahidAsghari ave, Emamat boulvard
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Dr. Mohamad Motazaker
Street address
Jahad square, research council
City
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
Associate proffessor
Other areas of specialty/work
Street address
No34, 16 meter, shahidAsghari ave, Emamat boulvard
,
City
Urmia
Postal code
Phone
+98 914 143 5104
Fax
Email
fm.tolooei@umsu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Fardin Mirzatolooei
Position
Associate proffessor
Other areas of specialty/work
Street address
No34, 16 meter, shahidAsghari ave, Emamat boulvard
City
Urmia
Postal code
Phone
+98 914 143 5104
Fax
Email
fm.tolooei@umsu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Fardin Mirzatolooei
Position
Associate professor
Other areas of specialty/work
Street address
Emam Khomeini Hospital
City
Urmia
Postal code
Phone
+98 44 1345 7287
Fax
Email
fardin_tolouei@yahoo.com.ac.irfm.tolooei@umsu
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*