

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of full weight bearing results immediately after surgery compared with Partial weight bearing in the first month after surgery in patients with anterior cruciate ligament rupture: A randomized clinical trial

Protocol summary

Study aim

The purpose of this study is to evaluate the results of two treatment methods (full weight bearing immediately after surgery and Partial weight bearing in the first month after surgery) in patients with Anterior Cruciate Ligament (ACL) tear

Design

Double-Blind randomized clinical trial (random block size: 4, via online Random allocation software), includes 84 patients in the two groups experimental and control group and phase 3 study

Settings and conduct

In this double blind randomized clinical trial, patient's sufferer Anterior Cruciate Ligament (ACL) rupture will be enrolled. This study includes patients referred to our orthopedic academic center (Poursina hospital) who are candidates for ACL reconstructive surgery and they will be divided randomly to two groups of full weight bearing immediately after surgery and Partial weight bearing in the first month after surgery

Participants/Inclusion and exclusion criteria

Inclusion criteria: Anterior Cruciate Ligament (ACL) rupture defined as +3 Lachman test in physical examination confirmed by Knee MRI as complete rupture Individuals aged from 18 to 50 Individual consent for participation in the study Exclusion criteria: Any history of knee surgery History of ACL rupture in opposite knee Any injuries in knee ligaments Abnormal radiography of the knee. (Including varus above 15 degrees) Any sign or symptom in hip or ankle.

Intervention groups

Experimental group: full weight bearing immediately after surgery Control group: Partial weight bearing in the first month after surgery in patients with anterior cruciate ligament rupture

Main outcome variables

time to return to exercise, quality of return to exercise, range of motion, Lachman test (+3 - 0), Knee Injury and Osteoarthritis Outcome Score (KOOS), , Lysholm Score, International Knee Documentation Committee (IKDC), Pain during kneeling, Anterior knee pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110809007274N17**

Registration date: **2022-02-10, 1400/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-10, 1400/11/21**

Update count: **0**

Registration date

2022-02-10, 1400/11/21

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-25, 1400/11/05
Expected recruitment end date
 2022-06-20, 1401/03/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Evaluation of full weight bearing results immediately after surgery compared with Partial weight bearing in the first month after surgery in patients with anterior cruciate ligament rupture: A randomized clinical trial

Public title
 full weight bearing immediately after surgery and Partial weight bearing in the first month in anterior cruciate ligament rupture

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Anterior Cruciate Ligament (ACL) rupture defined as +3 Lachman test in physical examination confirmed by Knee Magnetic resonance imaging (MRI) as complete rupture Individuals aged from 18 to 50 Individual consent for participation in the study
Exclusion criteria:
 Any history of knee surgery History of Anterior Cruciate Ligament (ACL) rupture in opposite knee Any injuries in knee ligaments Abnormal radiography of the knee (including Varus above 15 degrees) Any sign or symptom in hip or ankle

Age
 From **18 years** old to **50 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **84**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this study estimated sample size is 84 patients and randomization will be applied using random block design (block size: 4, via online Random allocation software). So, 21 quadruple blocks will be obtained and 42 patients will be in group A and 42 patients in group B. List of patients is kept in orthopedic research center in a sealed envelope and will be read daily after the study begins.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In current Double-Blind randomized clinical trial, patients are unaware about when and how to weight bearing. Also, evaluating researcher will be different from the person doing the study intervention. Two orthopedic assistants will be used for this purpose.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Guilan university of medical sciences

Street address

Poursina Hospital, Poursina Crossroads, Rasht, Guilan, Iran

City

Rasht

Province

Guilan

Postal code

41937-13194

Approval date

2022-01-12, 1400/10/22

Ethics committee reference number

IR.GUMS.REC.1400.493

Health conditions studied

1

Description of health condition studied

Anterior Cruciate Ligament (ACL) rupture

ICD-10 code

S83.51

ICD-10 code description

Sprain and strain of knee: Distortion of anterior cruciate ligament

Primary outcomes

1

Description

Time to return to exercise

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Ask the patient

2

Description

Quality of return to exercise

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Ask the patient

3

Description

Range of motion

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

According to the surgeon's report

4

Description

International Knee Documentation Committee (IKDC)

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Based on IKDS questionnaire

5

Description

Knee Injury and Osteoarthritis Outcome Score (KOOS)

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Based on KOOS questionnaire

6

Description

Lachman test

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

According to the surgeon's report

7

Description

Lysholm Score

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Based on Lysholm questionnaire

8

Description

Anterior knee pain

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Ask the patient

9

Description

Pain during kneeling

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Full weight bearing immediately after surgery

Category

Treatment - Other

2

Description

Control group: Partial weight bearing in the first month after surgery in patients with anterior cruciate ligament rupture

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

dr. Mohsen Mardani-kivi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

dr. Mohammadreza Naghipour

Street address

Namjoo St, Shahid Siadati St, in front of 17 Shahrivar Hospital, Rasht, Guilan, Iran

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

dr. Mohsen Mardani-kivi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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zoleikha azari

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Ph.D student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available