

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison effectiveness of Accelerated Versus Modified Accelerated Rehabilitation After ACL Reconstruction

Protocol summary

Study aim

The aim of this study was to compare the results of early rehabilitation with modified early rehabilitation after reconstructive surgery of the anterior cruciate ligament of the knee.

Design

This study includes is a clinical trial that using envelopes 120 patients candidates for anterior cruciate ligament reconstructive surgery randomly assigned to two groups of 60 intervention (Modified early rehabilitation) and control (early rehabilitation).

Settings and conduct

The study will be done in the orthopedic ward of Besat Hospital in Hamadan. The study will be single- blind. In this way, the person who evaluating the outcome of the surgery will be unaware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Participants in the study will be patients candidates for anterior cruciate ligament repair surgery. Inclusion criteria Patients with anterior cruciate ligament injury of the knee with body mass index above 30. Exclusion criteria include: anterior cruciate ligament rupture with meniscus injury, requires concomitant stotomy, with cartilage damage, and requires cartilage reconstruction and patients with multi-ligament rupture.

Intervention groups

Patients in the intervention group start flexion and extension movements of the knee from the day after surgery and are emphasized that the goal is to achieve at least 90 degrees of range of motion of the knee during the first 2 weeks. The control group is those who within 7-10 days First, in order to gain the range of motion of the knees, they are released, they are not trained. After 7-10 days, both groups will be visited and the same classical physiotherapy begins.

Main outcome variables

The main consequence of the intervention is to obtain at least 90 degrees of range of motion of the knee during

the first 2 weeks after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N13**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Of Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effectiveness of Accelerated Versus Modified Accelerated Rehabilitation After ACL Reconstruction

Public title

Rehabilitation After ACL Reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ACL isolation rupture

Exclusion criteria:

ACL rupture requiring simultaneous stotomy around the knee ACL ligament rupture and cartilage damage require cartilage repair Multi-ligament rupture

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 120 cards and write letter I on 60 for Intervention and on the other 60 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter (I or C) patients will be assigned to intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, the individual who measures the final outcome of the intervention in both groups will be unaware of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical

Science

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Shahid Fahmideh avenue, Hamadan, Iran

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Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.UMSHA.REC.1398.254

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

Sprain of cruciate ligament of knee

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

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

Changes in knee range of motion

Timepoint

The first, second, fourth weeks and third and sixth months after surgery

Method of measurement

Goniometer

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

Changes in daily performance and exercise activity

Timepoint

The first, second, fourth weeks and third and sixth months after surgery

Method of measurement

IKDC-2000 questionnaire

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

Intervention group: Patients will begin to walk one day after the surgery and the flexion and extension movements of the knee begin in them. They will be told that the goal is to get at least 90 degrees of knee range in the first two weeks

Category

Rehabilitation

2

Description

Control group: Patients will begin to walk one day after the surgery and the flexion and extension movements of the knee begin 7-10 days after surgery.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Gholamreza Ghorbani Amjad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available