Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 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

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Name of organization / entity
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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 Univercity of Medical Science
Street address
Shahid Fahmideh avenue, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
6517838697
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

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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
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
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Hamedan University of Medical Sciences
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Coach
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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