Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of muscle setting exercise before anterior cruciate ligament surgery versus control group on balance and strength of quadriceps and hamstring muscles: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of muscle setting exercise before anterior cruciate ligament surgery versus control group on balance and strength of quadriceps and hamstring muscles

Design
This is a randomized clinical trial, phase II, in which 30 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients undergoing anterior cruciate ligament surgery and referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years, Indication for anterior cruciate ligament surgery, Exclusion criteria: History of anterior cruciate ligament surgery

Intervention groups
Intervention group: Muscle setting exercise of quadriceps and hamstring muscles 45 minutes daily, 3 days a week, for 2 weeks before surgery and routine rehabilitation setting exercise 45 minutes daily, 3 days a week, for 6 weeks after surgery Control group: Routine rehabilitation setting exercise 45 minutes daily, 3 days a week, for 6 weeks after surgery

Main outcome variables
Primary outcome: Balance and strength of quadriceps and hamstring muscles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N388**
Registration date: **2021-03-14, 1399/12/24**
Registration timing: **prospective**

Last update: **2021-03-14, 1399/12/24**
Update count: **0**

Registration date
2021-03-14, 1399/12/24

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-06-05, 1400/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of muscle setting exercise before anterior cruciate

ligament surgery versus control group on balance and strength of quadriceps and hamstring muscles: a randomized clinical trial

Public title
Effect of muscle setting exercise before anterior cruciate ligament surgery versus control group on balance and strength of quadriceps and hamstring muscles
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 65 years, Indication for anterior cruciate ligament surgery,
Exclusion criteria:
History of anterior cruciate ligament surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
We will prepare two sheets of paper, writing on one sheet the name of the intervention and on another sheet the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all two sheets are drawn. The two paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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
Ethics Committee of Hamadan Buali Sina University
Street address
Vice-chancellor for Research and Technology, Hamadan Buali Sina University, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-10-15, 1398/07/23
Ethics committee reference number
IR.BASU.REC.1398.014

Health conditions studied

1

Description of health condition studied
Anterior cruciate ligament surgery
ICD-10 code
M23.61
ICD-10 code description
Other spontaneous disruption of anterior cruciate ligament of knee

Primary outcomes

1

Description
Balance and strength of quadriceps and hamstring muscles
Timepoint
Before surgery and 6 weeks after that
Method of measurement
Using dynamometer machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Muscle setting exercise of quadriceps and hamstring muscles 45 minutes daily, 3 days a week, for 2 weeks before surgery and routine rehabilitation setting exercise 45 minutes daily, 3 days a week, for 6 weeks after surgery
Category
Treatment - Other

2

Description
Control group: Routine rehabilitation setting exercise 45 minutes daily, 3 days a week, for 6 weeks after surgery
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital in Hamadan city

Full name of responsible person
Mahtab Pirani

Street address
Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Gholam Hosein Majzubi

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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

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mahtab Pirani

Position
Student of Physical Education and Sports Sciences

Latest degree
Master

Other areas of specialty/work
Rehabilitation management

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Ph.D.

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Person responsible for updating data

Contact

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