

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3364 0030

**Email**

Pirani.mb60@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Hosein Majzubi

**Street address**

Hamadan Buali Sina University, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 1601

**Email**

info.research@basu.ac.ir

**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

**Street address**

Faculty of Sports Sciences, Hamadan Buali Sina University, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 1601

**Email**

Pirani.mb60@gmail.com

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Yalfani

**Position**

Sports Rehabilitation Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Rehabilitation management

**Street address**

Faculty of Sports Sciences, Hamadan Buali Sina University, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 1601

**Email**

ali\_yalfani@yahoo.com

### Person responsible for updating data

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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