

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Effectiveness of the knee sleeve equipped with vibrator in comparison with custom knee sleeve on knee function in individuals with anterior cruciate ligament reconstruction

#### Protocol summary

##### Study aim

The evaluation of the effect of the neoprene knee sleeve equipped with a local muscle vibrator in comparison with a conventional neoprene knee sleeve on the ability to adapt to injury and neuromuscular parameters in individuals with anterior cruciate ligament reconstruction

##### Design

A randomized clinical trial with parallel open-label control group

##### Settings and conduct

This study will be carried out at The Shiraz University of Medical Science. Participants in this study will be randomly assigned to the control and intervention groups. Before receiving the orthotic intervention, the biomechanical tests will be taken from all participants in both groups. Then, the participants of this study will receive the orthotic intervention related to their groups and after 6 weeks of using the orthotic intervention, they will be biomechanically tested again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Individuals with anterior cruciate ligament reconstruction 2- Have isolated anterior cruciate ligament rupture 3-Ages of 18 and 40 Exclusion criteria: 1- Having significant deformities in lower limbs

##### Intervention groups

Intervention group: The soft knee sleeve equipped with local muscle vibrators Control group: The conventional soft knee sleeve

##### Main outcome variables

Level of daily activity; the electrical activity of the muscle

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160904029684N4**

Registration date: **2021-08-23, 1400/06/01**

Registration timing: **prospective**

Last update: **2021-08-23, 1400/06/01**

Update count: **0**

##### Registration date

2021-08-23, 1400/06/01

##### Registrant information

###### Name

Kourosh Barati

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 935 882 7110

###### Email address

barati.k@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-23, 1400/08/01

##### Expected recruitment end date

2022-04-21, 1401/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of the knee sleeve equipped with vibrator in comparison with custom knee sleeve on knee function

in individuals with anterior cruciate ligament reconstruction

### Public title

Effects of vibratory knee sleeve on people with anterior cruciate ligament reconstruction

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Body mass index in the range of 5-18-30 People aged 18 to 40 years Unilateral rupture and isolation of the anterior cruciate ligament confirmed by MRI A maximum of three months have elapsed since the injury Obtaining a score of 3-5 from the Tegner questionnaire (average level of activity)

#### Exclusion criteria:

Deformity in the lower extremities MRI-confirmed meniscus damage Associated cartilage damage Fractures or dislocations with ACL rupture History of fracture or previous surgery in the knee joint area Previous history of ACL or meniscus or other ligament damage

### Age

From **18 years** old to **40 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **20**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Participants in the research will be divided into two groups of intervention and control by simple random sampling. The free website [WWW.Randomization.com](http://WWW.Randomization.com) will be used for randomization.

### 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 Baqiyatallah University of Medical Sciences

##### Street address

Molasadra street

#### City

Tehran

#### Province

Tehran

#### Postal code

1435916471

#### Approval date

2021-05-10, 1400/02/20

#### Ethics committee reference number

IR.BMSU.REC.1400.025

## Health conditions studied

### 1

#### Description of health condition studied

Anterior cruciate ligament rupture

#### ICD-10 code

M23.619

#### ICD-10 code description

Other spontaneous disruption of anterior cruciate ligament of unspecified knee

## Primary outcomes

### 1

#### Description

Level of electrical activity of the muscle

#### Timepoint

Before the intervention and 6 weeks after receiving the intervention

#### Method of measurement

Electromyography

### 2

#### Description

Level of activity of daily living

#### Timepoint

Before the intervention and 6 weeks after receiving the intervention

#### Method of measurement

Tegner questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Individuals in the intervention group will use a soft knee sleeve equipped with a local muscle vibrator for 6 weeks. The knee sleeve is made of neoprene tissue. In its structure, a local muscle vibrator will be used to stimulate the quadriceps muscle. The participants will be instructed to use the orthosis for at least 8 hours a day.

**Category**

Rehabilitation

**2****Description**

Control group: The participants in the control group will use a conventional soft knee sleeve for 6 weeks. The knee sleeve is quite similar to the neoprene knee sleeve equipped with a vibrator received by the intervention group, except having no vibrator in its structure. The participants will be instructed to use the orthosis for at least 8 hours a day.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shiraz University of Medical Science

**Full name of responsible person**

Alireza Shamsodini

**Street address**School of Rehabilitation Science, Chamran Ave.,  
Shiraz**City**

Shiraz

**Province**

Fars

**Postal code**

3366971947

**Phone**

+98 71 3627 1552

**Email**

Rehab@Sums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad taghi Karimi

**Street address**School of Rehabilitation Science, Chamran Ave.,  
Shiraz, Iran**City**

Shiraz

**Province**

Fars

**Postal code**

3366971947

**Phone**

+98 71 3627 1552

**Email**

Rehab@Sums.ac.ir

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

Yes

**Title of funding source**

Shiraz 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**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Alireza Shamsodini

**Position**

Research Assistant Professor of Exercise Physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

**Street address**

Mollasadra street

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8804 0060

**Email**

shamseddin23@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Alireza Shamsodini

**Position**

Research Assistant Professor of Exercise Physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

**Street address**

Mollasadra street

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8804 0060

**Email**

Shamseddin23@gmail.com

**Postal code**

1435916471

**Phone**

+98 21 8804 0060

**Email**

Shamseddin23@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Alireza Shamsoddini

**Position**

Research Assistant Professor of Exercise Physiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

**Street address**

Mollasadra street

**City**

Tehran

**Province**

Tehran

**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**

Not applicable

**Informed Consent Form**

No - There is not 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**

Not applicable

**Data Dictionary**

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