

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 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 addressSchool 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 addressSchool 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