

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of hybrid knee brace on coping ability and neuromuscular parameters after acute anterior cruciate ligament tear

#### Protocol summary

##### Study aim

The effect of hybrid knee brace, consisting of a functional brace and an elastic sleeve, after acute rupture of ACL, on coping ability and neuromuscular parameters after acute injury of the anterior cruciate ligament.

##### Design

Clinical trial with community based and practice-oriented test and control group, with parallel groups, single-blind, simple randomization method

##### Settings and conduct

Sampling at Shafa Yahyaiyan Hospital, evaluation at the Sport Sciences Research Institute of Iran by the Biodex system 4 dynamometer and relevant questionnaires, tests include maximum muscle strength of the quadriceps, then 30% and 50% of MVC for assessing steadiness of Quadriceps, duration of 6-meter single-leg hop test will be recorded, one-way blindness

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: people between 18 to 40 years old; unilateral and isolated ACL rupture; maximum three months after injury; 3-5 grade of the Tegner Questionnaire; no cartilage damage; lack of fracture or dislocation; no history of fracture and previous surgery in the knee joint; no history of previous ACL or meniscal or other ligaments injuries. Exclusion criteria: unwillingness to continue cooperation; failure to comply with the rehabilitation protocol; knee pain and inflammation during the performance tests.

##### Intervention groups

Samples allocation from patients with complete anterior cruciate ligament rupture referring to the knee clinic at Shafa Yahyayan Hospital. The intervention in the test group includes a custom knee brace fabricated by taking measures of the individual's body, plus an appropriate size of sleeve, In the control group, there is no orthosis intervention, and people receive only physical therapy.

##### Main outcome variables

Coping condition of patients; Tampa questionnaire score; duration of a six-meter hop test; steadiness of the sub

maximal muscular force of the quadriceps

#### General information

##### Reason for update

The start and end dates of patient recruitment and the end date of the clinical trial were recorded.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181003041219N1**

Registration date: **2018-11-03, 1397/08/12**

Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **1**

##### Registration date

2018-11-03, 1397/08/12

##### Registrant information

##### Name

Zahra Nemati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8844 4530

##### Email address

zhrnem@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-03, 1397/08/12

##### Expected recruitment end date

2018-12-21, 1397/09/30

##### Actual recruitment start date

2018-12-01, 1397/09/10

##### Actual recruitment end date

2019-06-29, 1398/04/08  
**Trial completion date**  
2019-08-14, 1398/05/23

**Scientific title**  
The effect of hybrid knee brace on coping ability and neuromuscular parameters after acute anterior cruciate ligament tear

**Public title**  
The effect of hybrid knee brace on acute anterior cruciate ligament tear

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Unilateral isolated tear of anterior cruciate ligament  
Injury within last three month Required 3-5 scores from Tegner questionnaire  
**Exclusion criteria:**  
The presence of damage to the meniscus confirmed by MRI The presence of cartilage damage The presence of fracture or dislocation with ACL rupture The history of fracture and previous surgery in the knee joint The history of previous ACL or meniscal or other ligaments injuries

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

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **26**  
Actual sample size reached: **26**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, simple randomization method will be used. 26 cards, numbered from 1 to 26, are poured into the container. Then, each time, a card containing one number is randomly taken out of the container. In this way, 13 cards are selected and the registration number is considered as the numbers of test group. The remaining numbers in the container are considered as the control group. Subsequently, people entering the study according to inclusion criteria are randomized in the test or control group, respectively.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, blindness is done in one direction. So that the participants in the study do not know if they are in the control or test group. A specialist physician who will evaluate and refer patients will also be blind.

**Placebo**  
Not used

**Assignment**

Parallel

**Other design features**  
So far, a study based on orthosis intervention in the acute stage of the anterior cruciate ligament rupture has not been done to increase the number of copers. The result of the present study may increase the number of copers and reduce the likelihood of reconstruction surgery. Another aspect of this study is introducing a hybrid brace that benefits from the use of hard and soft braces simultaneously and also changes in the structure of the hard part for specific instability control after anterior cruciate ligament rupture. Finally, the effect of using the hybrid brace is evaluated by measuring the quadriceps steadiness, which indicates the level of coordination of the musculoskeletal system after the intervention.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Hemmat highway

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۳۹۶۱۴۵۳۵

#### Approval date

2018-07-10, 1397/04/19

#### Ethics committee reference number

IR.IUMS.REC.1397.049

## Health conditions studied

### 1

#### Description of health condition studied

Anterior cruciate ligament rupture

#### ICD-10 code

S83.51

#### ICD-10 code description

Sprain of anterior cruciate ligament of knee

## Primary outcomes

### 1

#### Description

Quadriceps steadiness

#### Timepoint

Acute stage

#### Method of measurement

Biodex dynamometer

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Individuals with acute anterior cruciate ligament rupture, intervention including using a hybrid brace for one month, and performing routine physiotherapy for ten sessions to reduce pain, edema and increase knee range of motion, then determine the person's compatibility with injury and measure the stability of the quadriceps muscle by Biodex Isokinetic dynamometer

### Category

Rehabilitation

2

### Description

Control group: Individuals with acute rupture of the anterior cruciate ligament, routine intervention including ten sessions of physiotherapy to reduce pain, edema and increase knee range of motion, then determine the person's compatibility with injury and measure the stability of the quadriceps muscle by Biodex Isokinetic dynamometer

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shafa Yahyaiyan hospital

#### Full name of responsible person

دکتر ابولفضل باقری فرد

#### Street address

Mujahideen Islam Street

#### City

Tehran

#### Province

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#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Phone

+98 21 3354 2001

#### Email

zhrnem@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr.Seyed Kazem Malakooti

#### Street address

Hemmat Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8670 2503

#### Email

research@iums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Maryam Jalali

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Orthoses & Prosthesis

#### Street address

Madadkaran Alley, Shahnazari street, Mirdamad Blvd.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Maryam Jalali

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zahra Nemati

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Orthoses & Prosthesis

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not 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**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable