Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Biodox 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 Tagner 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

Tehram

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

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
Tehran
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.
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 7124
Email
marjalali@gmail.com

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
Orthoses & Prosthesis

Street address
Madadkaran Ave., Shahnazari St., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 7124

Email
marjalali@gmail.com

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

Street address
Madadkaran alley, Shahnazari St., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 7124

Email
zhrnem@gmail.com

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