

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Investigating the effect of training on sand on walking and running mechanics in people with anterior cruciate ligament injury

Protocol summary

Study aim

Fitness and running are one of the main activities of people. Anterior cruciate ligament rupture usually occurs during rotational and shear movements. The use of sand in short-term treatment programs can be beneficial, but no studies have been conducted on long-term exercise on sand. Therefore, the aim of this study was to investigate the effect of exercises on sand on the mechanics of walking and running in people with anterior cruciate ligament injury with flat feet.

Design

Clinical trial with control group, with parallel, randomized, pre-test and post-test groups on 15 patients and 15 healthy individuals. Excel software rand function was used for randomization.

Settings and conduct

Testing will be done in a biomechanics laboratory with dimensions of 10 x 6 meters. Subjects are tested after preparation using EMG devices and pre-force plate. Then both groups of subjects will be trained on sand for 8 weeks and will be tested again.

Participants/Inclusion and exclusion criteria

Inclusion criteria for people with ACL and peronite foot injury Exclusion criteria: History of lower extremity surgery over the past 5 years, spinal abnormalities, osteoporosis, fractures or gait disorders

Intervention groups

The experimental group of people with anterior cruciate ligament injury with ACL rupture will be trained on sand for 8 weeks. The effectiveness of this training course is evaluated using pre-test and post-test. Exercise may be helpful in improving and reducing the subjects' pain. The above exercises have no side effects.

Main outcome variables

The peak of the earth's reaction force; Time to reach the peak of the earth's reaction force; Free torque of the earth's reaction force; Frequency spectrum of muscle electrical activity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200912048696N1**

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

hamed sheikhalizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 4343 2602

Email address

hamed.sh2102@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of training on sand on walking and running mechanics in people with anterior cruciate ligament injury

Public title

Investigating the effect of training on sand on walking and running mechanics

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with peronitis injuries and feet

Exclusion criteria:

History of lower extremity surgery over the past 5 years
Spinal abnormalities, osteoporosis, fractures or gait disorders

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this type of sampling, each member of the defined community has an equal and independent chance to be included in the sample. Being independent means that the election of a member has no effect on the election of other members of society. In this sampling, the chances of representing the sample and the community without special bias and population increase increase. In this method, first the list of names of all members is obtained, then a score or number is assigned to each of them and the required number is selected using a table of random numbers. Because the study population is small, the lottery method is used, ie the names of the people are written on a piece of paper and placed inside the box, then the papers are taken out one by one until the desired sample size is complete.

Blinding (investigator's opinion)

Single blinded

Blinding description

The research has two groups, A group as control group. Subjects (test participants) will not be aware of the existence of two groups. Only the steps of taking the test will be explained to him.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Baqiyatallah Al-Azam Hospital

Street address

Mulla Sadra St., South Sheikh Baha'i St.

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.BMSU.BAQ.REQ.1399.050

Health conditions studied**1****Description of health condition studied**

Anterior cruciate ligament injury

ICD-10 code

S83

ICD-10 code description

Dislocation and sprain of joints and ligaments of knee

Primary outcomes**1****Description**

Walking and running mechanics

Timepoint

Pre-test will be done and after 8 weeks of post-test practice

Method of measurement

Bertec force plate - electromyography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: People with anterior cruciate ligament injury with a flat foot are trained on the sand for 8 weeks

Category

Treatment - Other

2**Description**

Control group: In the control group, people with anterior cruciate ligament injury with peronite foot only participate in pre-test and post-test. Only routine treatment is performed and no new intervention will be performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohaghegh Ardabili University Health and Wellness Center

Full name of responsible person

AmirAli Jafarnezhadgero

Street address

Mohaghegh Ardabili University, University Street

City

Ardebil

Province

Ardabil

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5619913131

Phone

+98 45 3352 0457

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behrooz.h@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

alireza shahriyari

Street address

Mulla Sadra St., South Sheikh Baha'i St

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Tehran

Province

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1435915371

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Email

hamed.sh2102@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

alireza shahriyari

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Majid Mafi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biomechanic

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The collected data will be made available to the public in the form of articles and dissertations after analysis.

When the data will become available and for how long

Access period 2 months after printing the results

To whom data/document is available

Instructor and the test taker

Under which criteria data/document could be used

Article and dissertation

From where data/document is obtainable

Supervisor

What processes are involved for a request to access data/document

Raw data cannot be published

Comments