

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of foot medial arch support on EMG parameters of hamstring muscles, as a supporter of the anterior cruciate ligament (ACL), in men athletes with flat-feet during back squat exercise in comparison with normal-feet subjects

Protocol summary

Study aim

Evaluating the effect of medial arch support on the hamstring muscles' EMG activity while doing squat exercise between flat-feet and normal-feet subjects

Design

The study was performed on two groups of subjects based on the type of the foot arch: the flat foot and the normal foot group as the control group. Eligible Individuals were examined by the examiner by using clinical navicular drop test; subjects with navicular dropping more than 9 mm as flat-feet subjects and those with a navicular dropping between 9-6 mm was considered as normal subjects. There were 12 participants for each group. Regarding simple intervention, randomization and blindness were not indicated.

Settings and conduct

The intervention was carried out using a prefabricated foot arch support, and the subject performed squat exercise in three foot positions, barefoot, worn shoe, and shoe +orthoses with three different weights based on the percentage of his one repetition maximum; 1RM (40%, 50% and 60%), and simultaneously the hamstring muscle electromyographic data were recorded. The study was done in Shiraz School of Rehabilitation Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men athletes with Flat-Feet deformity, Men athletes with Normal-Feet, Athletes who have been doing Back-Squat exercise at least for 6 months, Having a normal body mass index (BMI) ($18.5 < 25$) and 20-40 years old. Exclusion criteria: Any biomechanical defect that causes the athlete does not be able to do the squat, History of lower extremity surgery, Foot osteoarthritis, Lower limb injury in the last six months, Current pain in the foot and Pain during walking.

Intervention groups

The intervention was done by a prefabricated medial longitudinal arch support in athletes' shoes in both groups during the squat exercise

Main outcome variables

Root mean square of muscle electromyographic (EMG) data
Peak amplitude of EMG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181025041458N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **retrospective**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Mohsen Mirzaiekhoshalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3830 0825

Email address

mirmowj@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-04-17, 1391/01/29

Expected recruitment end date

2013-05-20, 1392/02/30

Actual recruitment start date

2013-05-03, 1392/02/13

Actual recruitment end date

2014-11-30, 1393/09/09

Trial completion date

2014-11-30, 1393/09/09

Scientific title

Evaluating the effect of foot medial arch support on EMG parameters of hamstring muscles, as a supporter of the anterior cruciate ligament (ACL), in men athletes with flat-feet during back squat exercise in comparison with normal-feet subjects

Public title

The effect of foot medial arch orthosis on the EMG of lower limb muscles

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Men athletes with Flat-Feet Men athletes with Normal-Feet Men athletes with history of doing Back-Squat exercise at least from 6 month ago Subjects with normal body mass index (BMI) (18.5-<25) Subjects with 20-40 years old

Exclusion criteria:

Any biomechanical defect that causes the athlete does not be able to do the squat History of lower extremity surgery Foot osteoarthritis Lower limb injury in the last six months Current pain in the foot Pain during walking

AgeFrom **20 years** old to **40 years** old**Gender**

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **24**Actual sample size reached: **24****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz University of Medical Science Faculty of Rehabilitation

Street address

Faculty of Rehabilitation, Abiverdi street 1, Chamran blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

7194733669

Approval date

2013-04-24, 1392/02/04

Ethics committee reference number

IR.SUMS.REC.1392.S6557

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

Flat-foot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

2**Description of health condition studied**

Knee anterior cruciate ligament sprain

ICD-10 code

S83.51

ICD-10 code description

Sprain of anterior cruciate ligament of knee

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

Root mean square (RMS) of hamstring muscles electromyographic (EMG) data

Timepoint

Before and after wearing shoes and arch support and in barefoot state

Method of measurement

Using disposable surface electromyographic (EMG) electrodes and wireless EMG apparatus (ME 6000, U.S.A)

2**Description**

Peak amplitude (PA) of hamstring muscles electromyographic (EMG) activity

Timepoint

Before and after wearing shoes and arch support and in barefoot state

Method of measurement

Using disposable surface electromyographic (EMG) electrodes and wireless EMG apparatus (ME 6000, U.S.A)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: prefabricated foot medial arch support with 2 degrees medial wedge

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Rehabilitation Sciences

Full name of responsible person

Mohsen Mirzaiekhoshalani

Street address

School of Rehabilitation Sciences, Abiverdi 1 Street, Chamran Blvd

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71345-1733

Phone

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Email

rsrc@sums.ac.ir

Web page address

<http://rehab.sums.ac.ir/en/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

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vcrdep@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

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Mirzaiekhoshalani

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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

Yes - There is 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Hamstring muscles electromyographic EMG data and
complet methodology of study

When the data will become available and for how long

12 months after publishing the article and for 6 months

To whom data/document is available

Researchers from univercities and reseach centers which
will be accepted by Shiraz university of medical sciences

Under which criteria data/document could be used

For helping better study planning in future studies

From where data/document is obtainable

Mohsen Mirzaiekhoshalani mirmowj@gmail.com

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

First of all please Email to mirmowj@gmail.com, after
then he will contact to his school to get their permission
to share the data, if they accept your request, data will
be send to you

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

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Mirzaiekhoshalani

Position

Student

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Master

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