Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 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
Age
From **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

City

Shiraz

Province

Fars

Postal code

71345-1733

Phone

+98 71 3627 1551

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

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Email

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

Street address

No 34, Alley 1.14, Amirkabir Blvd

City

Shiraz

Province

Fars

Postal code

7176678148

Phone

+98 71 3830 0825

Email

mirmowj@gmail.com

Person responsible for scientific 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
Street address
School of Rehabilitation Sciences - Abiverdi 1 St. - Chamran Blvd. - Shiraz - Iran
City
Shiraz
Province
Fars
Postal code
7176678148
Phone
+98 71 3830 0825
Fax
Email
mirmowj@gmail.com

Person responsible for updating data

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
Street address
No 34, Alley 1.14, Amirkabir Blvd
City
Shiraz
Province
Fars
Postal code
7176678148
Phone
+98 71 3830 0825
Email
mirmowj@gmail.com

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