

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation on correlation between use of foot arc support and, Foot Pain and Tenderness, ankle strain and sprain in the population of soldiers in Shahid Hasheminejad garrison

Protocol summary

Summary

Objectives: Investigation of relation between use of foot arc support and Foot Pain and Tenderness, Sprain and strain in soldiers of Shahid Hasheminejad Garrison (2) Design: Randomized, Not blinded ,Single centered (3)Setting and conduct: Soldiers entering the Garrison who meet the inclusion criteria are asked to complete a questionnaire regarding their demographic info, they are asked about past history of trauma or any intermittent or persistent pain in their lower limb. Then they are examined regarding flat foot, cavus, halux valgus and tenderness in any part of their lower limb below the knees. Then the soldiers are divided to a case and a control group according to Table of Random Numbers. Soldiers in the case group are given a Foot Arc Support to wear inside their martial boots and nothing is given to the control group. The two groups are followed regarding pain and tenderness in defferent parts of the lower limb and ankle sprain and strain and their severity according to VAS pain scale. (4)Participants including major eligibility criteria: Study population: Soldiers entering Hasheminejad Garrison in Neyshabur in April 21st Inclusion criteria: Foot arc must not be less than 1.5 cm No history of lower limb fracture Exclusion criteria: Soldiers who does not use foot arc support for any reason Population size: 580 Alpha: 0.05 Beta=0.2 P1=0.3 P2=0.2 (5)Intervention: Foot arc supports which are made of polyurethane are allocated to soldiers in the case group according to their foot size and nothing will be given to the other group.They will be followed for sprain and strain and different foot parts pain and tenderness occurrence during the 2-months period of their military service. Intervention period: April 21st 2014 to June 21st 2014 (7)Main outcome(Measures and Variables) : Strain, Sprain, Pain and tenderness in different foot parts, Pain severity according to VAS, Occurrence of swelling and echymosis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030916914N1**

Registration date: **2014-08-15, 1393/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

Name

Saman Nazemian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research dean of Baqiatallah University of Medical Sciences, Baqiatallah Hospital, Trauma Research Center

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation on correlation between use of foot arc support and, Foot Pain and Tenderness, ankle strain and sprain in the population of soldiers in Shahid Hasheminejad garrisongarrison

Public title
Effect of Foot Arc Support in prevention of Foot Pain and Tenderness,ankle strain and sprain

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: The arc of the foot must not be less than normal (the arc height should be at least about 1.5 cm); The difference between the actual size of the the lowers limbs must not be more than 1 cm; No history of fracture in the lower limbs must be present; Must not be a professional athlete in football, volleyball, basketball or judo, taekwondo or other martial sports; Body Mass Index (BMI) must not be less than 20; Must not be exempted from marching by physician's order; Exclusion criteria If for any reason the soldier does not use the support or it goes wrecked; If the soldier is discharged from the military service for any reason;

Age
From **18 years** old to **35 years** old

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **580**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in Research Committee, Baqiatallah University of Medical Sciences

Street address
Baqiatallah University, Sheikh bahae St.

City
Tehran

Postal code

Approval date
2013-10-27, 1392/08/05

Ethics committee reference number
S340/3/6434 number 70- #33

Health conditions studied

1

Description of health condition studied

Stress Fracture

ICD-10 code

M84.3

ICD-10 code description

Stress fracture, not elsewhere classified Stress fracture NOS

2

Description of health condition studied

Ankle Sprain and Strain

ICD-10 code

S93.4

ICD-10 code description

Calcaneofibular (ligament) Deltoid (ligament) Internal collateral (ligament) Talofibular (ligament) Tibiofibular (ligament), distal

Primary outcomes

1

Description

Stress Fracture

Timepoint

During the 2 months period of military service

Method of measurement

stress fracture symptoms are introduced to the soldiers and when they feel pain in their foot they will come to the clinic and an X-ray of the foot will be ordered, if there was a fracture, the diagnosis is definite

2

Description

Ankle strain and sprain

Timepoint

During the 2 months period of military service

Method of measurement

Ankle sprain and strain symptoms are introduced to the soldiers, if it happens they come to the clinic and they will be examined for swelling or echymosis in the following days.

Secondary outcomes

1

Description

Tenderness in different parts of the foot

Timepoint

At the beginning and the end of the 2 months period of military service

Method of measurement

By touching firmly on tibia shin, ankle, calcaneum and metatarses the physician asks about feeling pain.

2

Description

Pain in different parts of the foot

Timepoint

At the beginning and the end of the 2 months period of military service

Method of measurement

Without touching on tibia shin, ankle, calcaneum and metatarses the physician asks about feeling pain and measuring pain severity according to VAS method by showing its pictures to the soldiers.

Intervention groups

1

Description

Soldiers who meet the inclusion criteria are divided into two groups according to random numbers table, foot arc support which is made of polyurethane is allocated to one group and nothing will be given to the other group. Foot arc support is believed to help to deliver the force along a bigger area of the foot sole and therefore reduce the pressure. The soldiers will be followed for stress fracture, sprain and strain and different foot parts pain and tenderness occurrence.

Category

Prevention

2

Description

An ordinary martial boot will be given to the control group. They will experience same martial exercises as the intervention group. They will also be followed for occurrence of different foot part pain and tenderness and ankle strain and sprain during the 2-months period of their military service.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hasheminejad Garrison, Baqrud

Full name of responsible person

Dr Majdi

Street address

10km from Neyshabur, on Neyshabur Broad

City

Neyshabur

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Research in Baqiatallah Medical University, Trauma Research Center

Full name of responsible person

Mr Rasuli

Street address

Baqiatallah Hospital, Sheikh bahae St., Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Research in Baqiatallah Medical University, Trauma Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Medicine

Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty