

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

Mashhad University of Medical Sciences, Faculty of Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1764 7307

##### Email address

nazemians861@mums.ac.ir

##### 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 garrisiongarrison

**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**

Saman Naazemyaan

##### **Position**

Medical Student

##### **Other areas of specialty/work**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Web page address****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*