

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of custom-made foot orthoses on pain and function in subjects with lower back pain and flatfoot

#### Protocol summary

##### Summary

1) Objectives: Evaluation of effectiveness of custom-made foot orthoses for reducing pain and improving function in subjects with lower back pain and flatfoot 2) Study design: A randomized, single-blinded, control group with a placebo 3) Setting and conduct: Participants with flatfoot and chronic or recurrent low back pain will randomly allocate to two groups: treatment and control. Treatment group will treat with the custom-made foot orthoses, and control will treat with prefabricated orthoses. Low back pain was evaluated by a visual analog scale for pain and Oswestry's Disability Index Questionnaire for lower back pain at four moments—on the day of inclusion in the study and after 6,12 and 24 weeks of using the orthoses. 4) Participants: Subjects between 18-35 years old with chronic non-specific low back pain who have flatfoot will included and any pathologic or non-mechanical low back pain and previous use of foot orthoses will excluded. 5) Intervention: One pair custom-made foot orthoses for treatment group that after the foot scan, foot orthoses was made based of each subject's foot and was administered immediately after preparation. In control group one pair prefabricated orthoses was administered. 6) Main outcome: Low back pain which is evaluated by a visual analog scale(VAS) and function which is evaluated by Oswestry's Disability Index Questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015113025308N1**  
Registration date: **2016-01-05, 1394/10/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-01-05, 1394/10/15

##### Registrant information

###### Name

Maryam Mirshahi

###### Name of organization / entity

Sina Specialized & Subspecialty Hospital, Teharn  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6634 8569

###### Email address

m-mirshahi@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Deputy of Research, Tehran University of Medical  
Sciences

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-06-21, 1395/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of custom-made foot orthoses on pain and  
function in subjects with lower back pain and flatfoot

##### Public title

The effect of custom-made foot orthoses on low back  
pain

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: subjects between 18-45 years old with pain between T12 and the S1 joints: presence of chronic non-specific low back pain for at least 6 weeks or recurrent low back pain for 3 months: Foot Posture Index (FPI-6) indicating at least +6 Exclusion criteria: any pathologic or non-mechanical low back pain: history of foot surgery, foot or lower extremity trauma or other conditions that may affect the measurement of this study: previous use of orthoses: leg length discrepancy greater than 5 mm: peripheral neuropathy due to disorders such as diabetes

### **Age**

From **18 years** old to **45 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **62**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee, Tehran University of Medical Sciences

##### **Street address**

Tehran University of Medical Sciences, Qods Aven., Keshavarz Blv., Tehran, Iran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2015-11-25, 1394/09/04

#### **Ethics committee reference number**

IR.TUMS.REC.1394.1276

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Low back pain

#### **ICD-10 code**

M54.5

#### **ICD-10 code description**

Low back pain

## **Primary outcomes**

### **1**

#### **Description**

level of pain

#### **Timepoint**

on the day of inclusion in the study, 6th week, 12th week, 24th week

#### **Method of measurement**

Visual Analogue Scale (VAS)

### **2**

#### **Description**

level of function

#### **Timepoint**

on the day of inclusion in the study, 6th week, 12th week, 24th week

#### **Method of measurement**

Oswestry Disability Index Questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Foot pain

#### **Timepoint**

at first visit, then every 4 weeks

#### **Method of measurement**

Question of subjects

## **Intervention groups**

### **1**

#### **Description**

Control group: one pair prefabricated foot orthoses made with polyester adjusting in to the size of the foot and fitting it into the shoes without change base of the foot mold. Instructions were given to the patients for gradual wearing the foot orthoses to discomfort and after 2 weeks, at least, 8h/day.

#### **Category**

Other

### **2**

#### **Description**

Intervention group: one pair custom-made foot orthoses made with polypropylene from heel to just behind the metatarsal heads. Instructions were given to the

participants for gradual wearing the foot orthoses to discomfort and after 2 weeks, at least, 8 h/day.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sports Medicine Clinic, Sina Specialized & Subspecialty Hospital

**Full name of responsible person**

Maryam Mirshahi, MD, Sports Medicine Specialist

**Street address**

Sina Hospital, Imam Khomeini Ave., Hassan Abad Sq., Tehran, Iran

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Sports and exercise department, Imam Khomeini Hospital

**Full name of responsible person**

Maryam Mirshahi, MD, Sports Medicine Specialist

**Street address**

Imam Khomeini Hospital, End of Keshavarz Blv, Tehran, Iran

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Sports Medicine Clinic, Sports Medicine Research Center

**Full name of responsible person**

Maryam Mirshahi, MD, Sports Medicine Specialist

**Street address**

No 7, Al-e-Ahmad Highway, Sports Medicine Research Center, Tehran, Iran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Deputy of Research, Tehran University of Medical Sciences

**Full name of responsible person**

Masoud Yunesian, MD

**Street address**

Tehran university of Medical Science, Qods Aven., Keshavarz Blv., Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Deputy of Research, Tehran University of Medical Sciences

**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**

Sina Specialized & Subspecialty Hospital

**Full name of responsible person**

Maryam Mirshahi, MD

**Position**

Sports Medicine Specialist

**Other areas of specialty/work**

**Street address**

Sina Hospital, Imam Khomeini Ave., Hassan Abad Sq., Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 6634 8569

**Fax**

**Email**

m-mirshahi@razi.tums.ac.ir ;  
m.mirshahi2000@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sina Specialized & Subspecialty Hospital

**Full name of responsible person**

Maryam Mirshahi, MD

**Position**

Sports Medicine Specialist

**Other areas of specialty/work**

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**Email**

m-mirshahi@razi.tums.ac.ir ;

m.mirshahi2000@yahoo.com

**Web page address**

**Phone**

+98 21 6634 8569

**Fax**

**Email**

m-mirshahi@razi.tums.ac.ir;

m.mirshahi20002yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Sina Specialized & Subspecialty Hospital

**Full name of responsible person**

Maryam Mirshahi, MD

**Position**

Sports Medicine Specialist

**Other areas of specialty/work**

**Street address**

Sina Hospital, Imam Khomeini Ave., Hassan Abad

Sq., Tehran, Iran

**City**

Tehran

**Postal code**

## 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*