

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Review and comparison of ergonomic features of three types of insoles in prolonged standing tasks: a field study in a shoe manufacturing factory

#### Protocol summary

effectiveness of shoe insole interventions in standing tasks for the industrial and service sectors

#### Study aim

Determining and comparing ergonomic features of three types of medical insoles in long standing tasks

#### Design

This interventional study was performed without a control group, with a single, double-blind group with 20 male participants.

#### Settings and conduct

This study is done in a shoe manufacturing company. the method of doing the work is as follows: the selected medical insoles are provided to the subjects and each subject for three weeks (one type of insole per week) and the number of working days per week and in all The length of the shift will use medical insoles. At the beginning and end of each working day, The amount of pain and discomfort in different parts of the legs and lower limbs is questioned using the visual analogue scale. . To measure the pressure of the sole of the foot, this study uses FSR sensors, that will be glued to two soles. Also, at the beginning and end of each work shift, leg volume changes in three areas will be measured using a Gulick meter.

#### Participants/Inclusion and exclusion criteria

Gender of male with age range between 30 to 45 years  
People whose job requires standing for a long time  
Absence of musculoskeletal disorders and problems

#### Intervention groups

Selected insoles in this study include anti-stress silicone insoles, sensitive foot silicone insoles and visco elastic polyurethane insoles. The duration of the test for each subject is three weeks (one type of insole per week) and the number of working days per week and throughout the shift. The order of using the insoles for all people will be completely random and using the insole numbering method and then choosing randomly (lottery)

#### Main outcome variables

Introducing the best type of insole to reduce musculoskeletal disorders and disorders caused by prolonged standing Provide information on the

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20180902040923N2**

Registration date: **2021-09-17, 1400/06/26**

Registration timing: **prospective**

Last update: **2021-09-17, 1400/06/26**

Update count: **0**

##### Registration date

2021-09-17, 1400/06/26

##### Registrant information

##### Name

Mohamad Sadegh Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 4839

##### Email address

ghasemi.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-21, 1400/08/30

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Review and comparison of ergonomic features of three types of insoles in prolonged standing tasks: a field study in a shoe manufacturing factory

**Public title**  
Review and comparison of ergonomic features of three types of insoles in prolonged standing tasks: a field study in a shoe manufacturing factory

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Gender of male subjects with age range between 40 to 50 years Height and weight of 50th percentile Having 2 years of standing work experience People whose job requires standing for a long time (one shift). (In this study, a cutting job was selected for the study.) Placement in the standard range of spinal curvatures (thoracic vertebral kyphosis, lumbar lordosis, and cervical lordosis)  
**Exclusion criteria:**  
Absence of musculoskeletal disorders and problems  
Absence of neurological defects  
Lack of autoimmune diseases such as rheumatoid arthritis and ....  
Absence of cardiovascular disorders  
No history of doing heavy sports activities  
Absence of congenital disorders in the foot area such as flat feet, excessive arch of the foot, wrist and knee deviations  
No history of accidents and injuries in the foot area during the past year

**Age**  
From **30 years** old to **45 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **20**  
More than 1 sample in each individual  
Number of samples in each individual: **3**  
Each participant uses all three insole samples during the study

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The examiner (or in other words, the researcher) and the participants will not have a role in choosing the type of insole, but when placing the insole in the subject's shoes, the examiner will notice the type of insole, but this will not affect the work process. Because all output variables

are based on objective observations and opinions of the subject and the researcher will only be in charge of process management.

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**  
-

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Iran University of Medical Sciences  
**Street address**  
Iran University of Medical Sciences, Hemat Highway next to Milad Tower, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535

**Approval date**  
2021-08-03, 1400/05/12

**Ethics committee reference number**  
IR.IUMS.REC.1400.034

**Health conditions studied**

**1**

**Description of health condition studied**  
Musculoskeletal Disorders

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**  
The amount of pain and discomfort in the lower extremities after using three types of insoles

**Timepoint**  
The beginning and the end of each day

**Method of measurement**  
Borg Pain Scale and Scale

**2**

**Description**  
The amount of volumetric changes in the leg after using three types of insoles

### **Timepoint**

The beginning and the end of each day

### **Method of measurement**

Using the Gulick meter

### **3**

### **Description**

The amount of foot pressure distribution after using three types of insoles

### **Timepoint**

the end of each day

### **Method of measurement**

FSR sensors

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

### **Description**

Intervention group: Intervention group: 20 men participated in the study. The duration of the test for each subject is three weeks (one type of insole per week) and the number of working days per week and throughout the shift. The order of using the insoles for all people will be completely random and using the insole numbering method and then choosing randomly (lottery).

### **Category**

Prevention

## **Recruitment centers**

### **1**

### **Recruitment center**

#### **Name of recruitment center**

shima shoes factory

#### **Full name of responsible person**

mohammad sadegh ghasemi

#### **Street address**

Iran University of Medical Sciences, Hemmat Highway next to Milad Tower, Tehran

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tehran

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ghasemi.m@iums.ac.ir

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Mohammad Sadegh Ghasemi

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### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Iran 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**

Iran University of Medical Sciences

#### **Full name of responsible person**

Mohammad Sadeq Ghasemi

#### **Position**

PhD in Biomechanics

#### **Latest degree**

Ph.D.

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

Ergonomics

#### **Street address**

Ergonomic Department, School of Public Health, Iran University of Medical Sciences, Hemat Express way, Tehran

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## Person responsible for scientific inquiries

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Associate professor

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## Person responsible for updating data

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Engineering

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available