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

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

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
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Sponsors / Funding sources

1

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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
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Mohammad Sadeq Ghasemi
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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