Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A comparison of the effect of anti-fatigue floor mat and viscoelastic shoe insole on preventing of low back pain due to prolonged standing in healthy subjects: An interventional study

Protocol summary

Summary

Objectives: The aim of this interventional study was to comparison the effect of anti-fatigue floor mat and viscoelastic shoe insole on electrical activities of the bilateral gluteus medius muscles and subjective low back pain (LBP) over prolonged standing. Design: 15 healthy participants with no history of LBP and without knowing the type of floor mats and shoe insoles were recruited to stand for 2 hours in four different standing positions which include; standing on the hard floor; standing on the anti-fatigue floor mat; using a placebo shoe insole while standing on the hard floor and the use of viscoelastic shoe insole while standing on the anti-fatigue floor mat. The interval period between the four trials for each participant was at least 7 days. Setting and conduct: In each position, at the beginning of the 2 hours standing protocol and at every 15 minutes during 2 hours standing, electrical activities of the gluteus medius muscles were collected by continuous surface electromyography (EMG), for analysis of bilateral coactivation pattern. Subjective LBP over standing time also were collected by visual analogue scale (VAS). Participants: 15 healthy participants with no history of LBP and ability to stand for more than 4 hours were recruited. Interventions: In the present study, anti-fatigue floor mat and viscoelastic shoe insole as intervention were applied. Main outcome measures: Pattern of bilateral gluteus medius muscles coactivation and subjective LBP.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016122430546N2**
Registration date: **2017-01-20, 1395/11/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2013-04-04, 1392/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of anti-fatigue floor mat and viscoelastic shoe insole on preventing of low back pain

due to prolonged standing in healthy subjects: An interventional study

Public title
A comparison of the effect of floor mat and shoe insole on low back pain due to prolonged standing

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Consent to participate in the study; the lack of any history of low back pain (LBP) requiring medical intervention or more than 3 days sick absence; any history of LBP over the past 12 months; no previous hip surgery; ability to stand for more than 4 hours; not having any kind of occupation requiring static standing over the past 12 months. Exclusion criteria: The lack of consent to participate in the study; having any history of LBP requiring medical intervention or more than 3 days sick absence; having any history of LBP over the past 12 months; having previous hip surgery; the lack of ability to stand for more than 4 hours; having any kind of occupation requiring static standing over the past 12 months.

Age
From **20 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences Central Site, Orjhans Street, Resalat Blvd, Urmia

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5714783734

Approval date
2013-03-05, 1391/12/15

Ethics committee reference number
جلسه شماره 105؛ تاریخ 91.12.15؛ بند 10 صورتجلسه

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
Gluteus medius muscles co activation

Timepoint
Every 15 minutes during 2 hours standing

Method of measurement
Electromyography

2

Description
Subjective pain

Timepoint
Every 15 minutes during 2 hours standing

Method of measurement
Visual analogus scales

Secondary outcomes

empty

Intervention groups

1

Description
The use of anti-fatigue floor mat while standing. Participants were instructed to stand in their usual manner, do not take any step, and do not lean on the table to rest their feet and to support their body weight.

Category
Prevention

2

Description
The use of viscoelastic shoe insole while standing on a hard floor. Participants were instructed to stand in their usual manner, do not take any step, and do not lean on the table to rest their feet and to support their body weight.

Category

Prevention

3

Description
The use of viscoelastic shoe insole while standing on the anti-fatigue floor mat. Participants were instructed to stand in their usual manner, do not take any step, and do not lean on the table to rest their feet and to support their body weight.
Category
Prevention

4

Description
Using a placebo shoe insole while standing on a hard floor. Participants were instructed to stand in their usual manner, do not take any step, and do not lean on the table to rest their feet and to support their body weight.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Iraj Mohebbi
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Urmia
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 Urmia 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
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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