

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The impact of 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 investigate the effect of 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 shoe insoles were recruited to stand for 2 hours in two different standing positions which include; using a placebo shoe insole and the use of viscoelastic shoe insole while standing on a hard floor. The interval period between the first and the second trial 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 co-activation 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, viscoelastic shoe insole as an intervention was applied. **Main outcome measures:** Pattern of bilateral gluteus medius muscles coactivation and subjective LBP.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016102930546N1**
Registration date: **2016-12-10, 1395/09/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-10, 1395/09/20

Registrant information

Name

Iraj Mohebbi

Name of organization / entity

Urmia University of Medical Sciences

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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

The impact of viscoelastic shoe insole on preventing of low back pain due to prolonged standing in healthy subjects: An interventional study

Public title

The impact of 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 a 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 a 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

Ethics committee of Urmia University of Medical Sciences

Street address

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

City

Urmia

Postal code

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

Intervention group: 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

2

Description

Control group: 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

Street address

Urmia University of Medical Sciences Central Site,
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Urmia University of
Medical Sciences

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

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Mahmoud Ghaderi

Position

Research assistant/ MSc

Other areas of specialty/work

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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