

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The Effect of Insoles With Different Wedge on Balance control With and Without Visual input before and after fatigue In healthy people

#### Protocol summary

##### Study aim

The main purpose of this study was to study The effect of Insoles with different Wedge on balance control with and without visual input before and after fatigue in healthy individuals

##### Design

This research was carried out at the Bu-Ali Sina University Rehabilitation Research Laboratory. Which includes pre-test and post-test in one session. Twenty female volunteers from the University who had normal navicular elevations participated in the study and performed equilibrium tests with three different insoles.

##### Settings and conduct

The Present study is a semi-experimental research based on the desing, the method os selecting the subject,the measurment tools and the intervention, and the research design was pre-test and post- test on one Sesión

##### Participants/Inclusion and exclusion criteria

no history of surgery, fracture, burn, musculoskeletal problems, back pain or severe trauma in the lower extremity during the last six months of the study and dominance of the right foot, as well as having normal navicular height the criteria for entering the research.Having lower limb damage, having a history of lower limb surgery, balance disorders such as Atrial System disorders, lower extremity abnormalities, spine and legs.

##### Intervention groups

A group of 20 people performed equilibrium tests using three types of insoles

##### Main outcome variables

Prevention of injury,Improved static and Dynamic balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171225038072N1**

Registration date: **2018-09-02, 1397/06/11**

Registration timing: **retrospective**

Last update: **2018-09-02, 1397/06/11**

Update count: **0**

##### Registration date

2018-09-02, 1397/06/11

##### Registrant information

###### Name

Azadeh Asgarpoor

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3436 7105

###### Email address

azadehasgarpoor@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-11-05, 1395/08/15

##### Expected recruitment end date

2017-01-10, 1395/10/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Insoles With Different Wedge on Balance control With and Without Visual input before and after fatigue In healthy people

##### Public title

The effect of the insoles on the Proprioception of the floor and ankle in balance control

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

no history of surgery fracture burn musculoskeletal problems back pain or severe trauma in the lower extremity during the last six months of the study and dominance of the right foot as well as having normal navicular height

#### Exclusion criteria:

Having lower limb damage having a history of lower limb surgery balance disorders such as Atrial System disorders , lower extremity abnormalities, spine and legs

### Age

From **20 years** old to **24 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

- Participant
- Investigator
- Data analyser

### Sample size

Target sample size: **20**

### Randomization (investigator's opinion)

N/A

### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The researcher has by no means interfered in test neither in pre-test and post-test.the tests were given by individuals who had not clue about the plan.the participants were not alter of test application as well and just acted to instruction.the person who analyzed the data did know about the study and generally looked at the data.

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

##### Street address

Pajohesh Intersection, Mahdieh Street

### City

Hamedan

### Province

Hamadan

### Postal code

65178

### Approval date

2017-11-11, 1396/08/20

### Ethics committee reference number

IR.UMSHA.REC.1396.652

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

در یک balance the

#### Timepoint

At the beginning of the study, when using the Insoles and at the same time after the fatigue

#### Method of measurement

Boyd System Balance

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Performing equilibrium tests using three types of insoles

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The University Bu Ali Sina

##### Full name of responsible person

Ali Yalfani

##### Street address

Pajohesh Intersection, Mahdieh street

##### City

Hamedan

##### Province

Hamadan

##### Postal code

38695\_65178

**Phone**

+98 81 3838 1422

**Email**

Ali\_Yalfani@Yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

The University of Bu-Ali Sina

**Full name of responsible person**

Gholam Hossein Majzoobi

**Street address**

University of Bu-Ali Sina , Pajohesh intersection,  
Mahdieh Street

**City**

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**Province**

Hamadan

**Postal code**

65178-38695

**Phone**

+98 81 3827 2072

**Email**

gh\_majzoobi@basu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

The University of Bu-Ali Sina

**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**

The University of Bu-Ali Sina

**Full name of responsible person**

Azadeh Asgarpoor

**Position**

Masters Student

**Latest degree**

Master

**Other areas of specialty/work**

Corrective Exercises and Sport Injuries

**Street address**

No. 4, Alley 44., Saadi east Street

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Position**

Masters Student

**Latest degree**

Master

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

The University Bu-Ali Sina

**Full name of responsible person**

Azadeh Asgarpoor

**Position**

Masters Student

**Latest degree**

Master

**Other areas of specialty/work**

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**Postal code**

8816784365

**Phone**

+98 32252809

**Email**

## Sharing plan

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

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

Yes - There is 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**

No - There is not a plan to make this available

### **Title and more details about the data/document**

Data and documentation can be shared, but with the

unidentifiable individuals and the private information of the subjects

### **When the data will become available and for how long**

Starting data access 1 year after printing results

### **To whom data/document is available**

Researchers in this field are allowed to act for documentation

### **Under which criteria data/document could be used**

Only the type of analysis that can be done in the research can be redefined

### **From where data/document is obtainable**

azadehasgarpoor@gmail.com

### **What processes are involved for a request to access data/document**

When an applicant submits a document for his / her work area in relation to the subject matter of the thesis and, if reasonable request, and the commitment not to misuse the data of this research , the data will be sent to him within1 week' of work

### **Comments**

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