

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Effect of Lateral Wedge Insole on Gait Initiation in Osteoarthritis of the Tibiofemoral Knee Joint

#### Protocol summary

##### Summary

Conservative management is considered as the cornerstone of knee osteoarthritis treatment. Balance and locomotion problems are still under question in mild knee osteoarthritis. Therefore, the aim of this study is considering posture and locomotion coupling in gait initiation and the effect of lateral wedge insole on gait initiation. Patients with mild knee osteoarthritis of the medial compartment of the tibiofemoral joint, pain more than 30 mm based on the Visual Analogue Scale, grade I and II of osteoarthritis are included in the study and patients with grade III and IV osteoarthritis are excluded. In this study 19 patients with mild knee osteoarthritis in the patients group and 19 healthy subjects as the control group are recruited. Each participant is evaluated in three conditions as the following: 1. Barefoot, 2. Participant's own shoes, 3. Lateral wedge insole embedded in the participant's shoes. Each participant put on the lateral wedge insole embedded in participants' shoes for 20 minutes for adaptation. In addition, the patients in knee osteoarthritis group use the lateral wedge insole in their own shoes for 5 to 10 hours in a day for one month and will be reexamined as the follow-up. For gait initiation evaluation, each participant stands on a single force plate and will take the forward first step by examiner command. Displacement and speed of center of pressure in three aforementioned conditions are recorded and measured as the main outcome measures.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016060628310N1**

Registration date: **2016-08-14, 1395/05/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-08-14, 1395/05/24

##### Registrant information

###### Name

Mohammad Ali Sanjari

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research and Technology of Iran University of Medical Sciences

##### Expected recruitment start date

2015-12-15, 1394/09/24

##### Expected recruitment end date

2017-01-01, 1395/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Lateral Wedge Insole on Gait Initiation in Osteoarthritis of the Tibiofemoral Knee Joint

##### Public title

The effect of lateral wedge insole on initiation of walking in Arthrosis of the knee joint

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion Criteria: Osteoarthritis of the medial compartment of the tibiofemoral joint based on the American College of Rheumatology (ACR) criteria; pain more than 30 mm based on the Visual Analogue Scale (VAS); grade I and II of osteoarthritis based on the Kellgren and Lawrence System (K&L) Exclusion Criteria: Isolated osteoarthritis of the patellofemoral joint; grade III and IV osteoarthritis; knee surgery; progressive depression syndrome; massage therapy; physical therapy; knee injection in the last month before participation in the study; change in analgesic medication in the last previous 24 hours; knee ligament injuries; knee alignment reconstruction; age younger than 35 years old or older than 65 years old; BMI more than 30 kg/m<sup>2</sup>; foot problems which prohibited use of lateral wedge insole, including, hallux valgus, foot pronation, flat foot, etc; visual and hearing problems

### **Age**

From **35 years** old to **65 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **38**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Iran University of Medical Sciences

##### **Street address**

School of Rehabilitation Sciences, Madadkaran Ave.,  
Shahnazari St., Madar Sq., Mirdamad Blvd.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2015-12-13, 1394/09/22

#### **Ethics committee reference number**

IR.IUMS.REC.1394.9211503210

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Mild Knee Osteoarthritis

#### **ICD-10 code**

M17.0

#### **ICD-10 code description**

Primary gonarthrosis, bilateral

## **Primary outcomes**

### 1

#### **Description**

Duration of Anticipatory postural adjustment

#### **Timepoint**

pre and 1 month after the intervention

#### **Method of measurement**

based on ms by single force plate

### 2

#### **Description**

Duration of monopedal phase

#### **Timepoint**

pre and 1 month after the intervention

#### **Method of measurement**

based on ms by single force plate

### 3

#### **Description**

Duration of bipedal phase

#### **Timepoint**

pre and 1 month after the intervention

#### **Method of measurement**

based on ms by single force plate

### 4

#### **Description**

Duration of APA1

#### **Timepoint**

pre and 1 month after the intervention

#### **Method of measurement**

based on ms by single force plate

### 5

#### **Description**

Duration of APA2

#### **Timepoint**

pre and 1 month after the intervention

#### **Method of measurement**

based on ms by single force plate

### 6

#### **Description**

Duration of LOC

#### **Timepoint**

pre and 1 month after the intervention  
**Method of measurement**  
based on ms by single force plate

## 7

**Description**  
Velocity of COP trajectory in APA1  
**Timepoint**  
pre and 1 month after the intervention  
**Method of measurement**  
Based on m/s by single force plate

## 8

**Description**  
Velocity of COP trajectory in APA2  
**Timepoint**  
pre and 1 month after the intervention  
**Method of measurement**  
Based on m/s by single force plate

## 9

**Description**  
Velocity of COP trajectory in LOC  
**Timepoint**  
pre and 1 month after the intervention  
**Method of measurement**  
Based on m/s by single force plate

## 10

**Description**  
Length of COP trajectory in APA1  
**Timepoint**  
pre and 1 month after the intervention  
**Method of measurement**  
based on m by single force plate

## 11

**Description**  
Length of COP trajectory in APA2  
**Timepoint**  
pre and 1 month after the intervention  
**Method of measurement**  
based on m by single force plate

## 12

**Description**  
Length of COP trajectory in LOC  
**Timepoint**  
pre and 1 month after the intervention  
**Method of measurement**  
based on m by single force plate

## 13

**Description**  
Total Duration of gait initiation  
**Timepoint**  
pre and 1 month after the intervention

**Method of measurement**  
based on ms by single force plate

## Secondary outcomes

### 1

**Description**  
Integral of anterior-posterior component of GRF in APA  
**Timepoint**  
Pre and 1 month after intervention  
**Method of measurement**  
Based on N/s by a single force plate

### 2

**Description**  
Integral of anterior-posterior component of GRF in monopodal phase  
**Timepoint**  
Pre and 1 month after intervention  
**Method of measurement**  
Based on N/s by a single force plate

## Intervention groups

### 1

**Description**  
Lateral wedge insole which is put under shoes inner sole. At baseline, participants wear their shoes and lateral wedge insoles for 20 minutes for adaptation. The patients in knee osteoarthritis group wear the lateral wedge insoles in their own shoes for 5 to 10 hours in a day for one month and then will be evaluated for the second time as follow-up.

**Category**  
Rehabilitation

### 2

**Description**  
Participant's shoes  
**Category**  
N/A

### 3

**Description**  
Barefoot  
**Category**  
N/A

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Firoozgar General Hospital  
**Full name of responsible person**  
Elham Esfandiari

**Street address**

Orthotics and Prosthetics Department, Rehabilitation school, Madadkaran Ave., Shahnazari St., Madar Sq., Mirdamad Blvd.

**City**

Tehran

<http://www.sanjari.ir>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Web page address**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Vice Chancellor of Research and Technology of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat Highway

**City**

Tehran

**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**

*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**

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**Full name of responsible person**

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Assistant Professor/PhD in Biomechanics

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**Web page address****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*