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 medical 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 commend. 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

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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 medical compartemnt 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 Kellgrene 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 then 35 years old or older than 65 years old; BMI more than 30 kg/m2; 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.

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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 monopedal 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.
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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
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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

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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