

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating The immediate Effect of Using Two density Insoles with Lateral Wedge Embedded inside a Novel Neoprene Sock on Pain, Quality of Life, and Biomechanical Parameters of the Knee Joint During walking in the Elderly with Medial Compartment Knee Osteoarthritis

Protocol summary

Study aim

Evaluating The immediate Effect of Using Two density Insoles with Lateral Wedge Embedded inside a Novel Neoprene Sock on Pain, Quality of Life, and Biomechanical Parameters of the Knee Joint During walking in the Elderly with Medial Compartment Knee Osteoarthritis

Design

Repeated measures one-grouped before-after trial, sample size =30

Settings and conduct

Sampling will be done by the sample of convenience method in Hamadan city. The biomechanics laboratory of the Boali University of Hamadan and the ergonomics laboratory of the Hamedan University of Medical Sciences will be equipped for collecting the kinematics and kinetics, respectively. Quality of life will be evaluated with a 36 SF questionnaire and pain intensity will be evaluated using a visual scale. The Intervention will be a medical insole with a 6-degree of heel and sole wedge on the lateral side for the affected side, ethyl vinyl acetate with a shore of 70 in the lateral half and shore of 20 in the medial half, supporting both the longitudinal and the transverse arches and embedded in a neoprene sock with a subtalar strap. The data will be collected at three conditions: bare feet, wearing shoes without medical insoles, and the use of insoles embedded in neoprene socks at 8-12 AM. Each test will repeat six times, so each person experiences a total of 36 tests. People will walk between 3 to 6 times with two minutes of rest between efforts.

Participants/Inclusion and exclusion criteria

Unilateral osteoarthritis of the Medial compartment of the knee, confirmed by a physician expert in orthopedics or physical medicine. The intervention has no adverse effect on the participants

Intervention groups

Two density Insoles with Lateral Wedge Embedded inside a Novel Neoprene Sock

Main outcome variables

pain, quality of life, ground reaction force, step length, step time, velocity, cadence, double limb support duration, step width,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058315N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Nahid Tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1633

Email address

n.tafti@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating The immediate Effect of Using Two density Insoles with Lateral Wedge Embedded inside a Novel Neoprene Sock on Pain, Quality of Life, and Biomechanical Parameters of the Knee Joint During walking in the Elderly with Medial Compartment Knee Osteoarthritis

Public title

Evaluating The Effect of Using Two density Insoles with Lateral Wedge in the Elderly with Medial Compartment Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

unilateral osteoarthritis of the medial compartment of the knee joint

Exclusion criteria:

Any symptom caused due to the negative effect of the intervention receiving any simultaneous treatment in the form of intra-articular injection or physical therapy the presence of any accompanying injury such as problems in the wrist and hip joints low back pain rheumatoid arthritis

AgeFrom **60 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****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**

Hamadan university of medical sciences

Street address

Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

6517754175

Approval date

2023-04-29, 1402/02/09

Ethics committee reference number

IR.UMSHA.REC.1402.081

Health conditions studied**1****Description of health condition studied**

osteoarthritis of the medial compartment of the knee joint

ICD-10 code

M19.90

ICD-10 code description

Unspecified osteoarthritis, unspecified site

Primary outcomes**1****Description**

pain

Timepoint

before and immediately after intervention

Method of measurement

visual analogue scale

2**Description**

Quality of life

Timepoint

before and immediately after intervention

Method of measurement

Persian version of S-F36 questionnaire

3**Description**

Spatiotemporal parameters of walking

Timepoint

before and immediately after intervention

Method of measurement

Qualysis motion capture system

4

Description

Ground Reaction Force

Timepoint

before and immediately after intervention

Method of measurement

Kistler Force platform

Secondary outcomes

empty

Intervention groups

1

Description

A pair of laced neoprene socks equipped with medical insoles will be provided to people with one-sided osteoarthritis of the internal compartment of the knee joint. The neoprene sock encompasses a medical insole and a strap is sewn to its upper to stabilize the subtalar joint, which prevents heel eversion and provides ankle stability. The insole will be made of ethyl vinyl acetate foam with two different densities, the lateral part with a hardness of A:70 and the medial with a hardness of A:20. The lateral half of the insole will also have a 6 mm heel and sole wedge. The design and fabrication of medical insoles will be done with the aid of a computer in the specialized foot clinic, Shahid Mobasher Rehabilitation Clinic, Hamadan. Data will be collected after 10 minutes of walking with the sock including the medical insole and the patient's accommodation achievement.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavana Physiotherapy center

Full name of responsible person

Akbar Sufizadeh

Street address

No. 6, Shahid Gheiratian Ave, Pastor Ave, Hamadan

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Phone

+98 918 546 4955

Email

Sufizadeh.Aakbar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

Shahid Fahmideh

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Hamadan

Province

Hamadan

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۶۵۱۷۸۳۸۶۷۸

Phone

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Email

Shokoohi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

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

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Tafti

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and prosthetics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nahid Tafti

Position

Assistant Professor

Latest degree

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Person responsible for updating data

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38381571

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to intellectual property rights, the data will be reported only in the form of published papers

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable