

# 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

**Age**From **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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517833131

**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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۶۷۸

**Phone**

+98 81 3131 4058

**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

**Street address**

Shahid Fahmideh

**City**

Hamadan

**Province**

Hamadan

**Postal code**

3716846419

**Phone**

+98 81 3838 1633

**Fax**

**Email**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Nahid Tafti

**Position**

Assistant Professor

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**Fax****Email**

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## Person responsible for updating data

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Hamedan University of Medical Sciences

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**City**

Hamadan

**Province**

Hamadan

**Postal code**

3716846419

**Phone**

38381571

**Email**

Na.Tafti@yahoo.com

## 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