

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study effect of the soft medical insole with lateral wedge on reducing pain, improving performance and quality of life of the elderly with knee osteoarthritis

Protocol summary

Study aim

Study effect of the soft medical insole with lateral wedge on reducing pain, improving performance and quality of life of the elderly with knee osteoarthritis.

Design

Clinical trial with control group and one-way blind on 30 patients. Lottery is used for randomization.

Settings and conduct

The research site is located in the orthopedic clinic of Isfahan University of Medical Sciences. Patients will complete 2 questionnaires before and one month after the start of the study and the quality of life and knee function pain will be assessed.

Participants/Inclusion and exclusion criteria

Young elderly 60 to 69 who have a history of pain and tenderness in the medial compartment.

Intervention groups

The intervention group receives a soft medical insole with 7 degrees of lateral wedge. This intervention reduces the weight pressure and ground reaction force in the internal compartment of the knee. The control group does not receive any payment and they only complete the questionnaires included in the appendix of the thesis

Main outcome variables

Knee joint pain, quality of life and knee function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220428054688N1**

Registration date: **2022-09-16, 1401/06/25**

Registration timing: **prospective**

Last update: **2022-09-16, 1401/06/25**

Update count: **0**

Registration date

2022-09-16, 1401/06/25

Registrant information

Name

zahra Abdolhosseinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study effect of the soft medical insole with lateral wedge on reducing pain, improving performance and quality of life of the elderly with knee osteoarthritis

Public title

Study effect of the soft medical insole with lateral wedge of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Young elderly aged 60 to 69 years and both sexes
 History of pain and tenderness in the internal compartment of the knee in the last six months
 Average knee pain of at least 3 on the (Visual Analogue Scale) VAS scale
 Tibiofemoral internal involvement and reduction of joint space Grade 1 to 3 in the inner part of the tibiofemoral in Kellgren Lawrence (K/L)
 Tendency to wear insoles for shoes for at least 4 hours a day.

Exclusion criteria:
 Intra-articular injection in the last six months
 History of any knee surgery or lower limb injury
 Inability to walk without assistance, cane or walker
 Involvement and osteophytes in the outer part of the tibiofemoral more than the inner
 Rheumatoid arthritis or other inflammatory arthritis, diabetic neuropathy
 Current use of knee braces or analgesics
 Body mass index (BMI) more than 30 kg per square meter
 Elderly people with cognitive and mental problems or low alertness and use of confusing and sleep-inducing drugs

Age
 From **60 years** old to **69 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple randomization based on lottery

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In this study, the participants are kept blind to the study. From numbers 1 to 30, each patient chooses a number by lottery. Every patient who took an even number out of the container is the intervention group and the odd number is the control group. The researcher who is responsible for evaluating the outcome and analyzing the data is aware of the details.

Placebo
 Not used

Assignment
 Parallel

Other design features
 Evaluation of the effect of soft medical insole with lateral wedge on knee osteoarthritis only in young elderly

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Nursing, Management and Rehabilitation of Isfahan University of M

Street address

Hezar jerib street' Isfahan' Iran

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-08-27, 1401/06/05

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.068

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain score

Timepoint

30 days

Method of measurement

From 2 questionnaires :Visual Analogue Scale (VAS), Knee Injury and Osteoarthritis Outcome Score (KOOS)

2

Description

Quality of Life

Timepoint

30 days

Method of measurement

Quality of Life Scale developed through the World Health Organization (bref)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: soft medical insoles of polyurethane type with hardness between 10 and 25 and will be

commercially available. The sole will have a 7-degree outer edge and a length equal to the length of the foot. The insole cover is synthetic leather and has an internal arch. People participating in the study must use insoles for 4 weeks and at least 4 hours a day, but they can wear them as long as they want. Insoles in shoes or in a chair that the person It will be commonly used in the past months. So that the shoes or sandals themselves do not have a positive or negative effect on the research variables.

Category

Rehabilitation

2

Description

Control group: does not receive any intervention. The control group with all the same conditions at the beginning of the project and after one month will complete the questionnaires attached to the proposal.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

zahra abdolhosseinpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Abdolhosseinpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Orthosis and prosthesis

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

Orthosis and prosthesis