

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of lateral wedge insole with and without subtalar strap on lateral trunk lean motion in knee osteoarthritis

#### Protocol summary

##### Summary

Purpose: To compare the effect of lateral wedge insole on lateral trunk lean motion in knee osteoarthritis to lateral wedge insole with subtalar strap. Method: 23 patients aged over 40 years with medial compartment knee osteoarthritis in one knee according to American College of Rheumatology criteria were participated in this study. They were excluded if they had bilateral knee osteoarthritis and secondary arthritis. Participants were tested in 3 conditions while walking through 3 meters walkway: without insole, lateral wedge insole and lateral wedge insole with subtalar strap. The insoles were made of High density Ethyl Vinyl Acetate with leather covered. They had 5 degree lateral wedge for involved limb and were neutral for contra lateral limb. A six camera Vicon motion analysis system was used to measure lateral trunk lean motion. 5 passive reflective markers were placed on left and right acromioclavicular joints, right and left anterior superior iliac spines and on sacrum. The immediate effect of lateral wedge insole with and without subtalar strap was compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104185520N4**

Registration date: **2011-04-29, 1390/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-29, 1390/02/09

##### Registrant information

##### Name

Mojtaba Kamyab

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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kamyab@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellor for Research, Tehran University of medical sciences

##### Expected recruitment start date

2010-11-22, 1389/09/01

##### Expected recruitment end date

2011-01-21, 1389/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of lateral wedge insole with and without subtalar strap on lateral trunk lean motion in knee osteoarthritis

##### Public title

The effect of lateral wedge insole with and without subtalar strap in patients with genoarthrosis

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion Criteria: 1. age between 35 to 50 years 2. at least 3 level of pain based on a ten level visual analogue scale 3. radiographic osteophyte at the joint space 4. normal or mild varus knee joint malalignment and unilateral medial tibiofemoral knee osteoarthritis 5.

grade I or II of knee osteoarthritis based on Kellgren and Lawrence knee osteoarthritis grading system. Exclusion Criteria: 1. bilateral knee osteoarthritis 2. grade III or higher of knee osteoarthritis 3. secondary knee osteoarthritis caused by trauma, knee joint surgery or other rare forms of arthritis 4. significant knee joint ligament laxity 5. previous knee joint fracture 6. therapeutic knee joint injection in previous 6 months 7. nervous system disorder that made some problems in voluntary movement 8. perception disorder 9. chronic back pain 10. lower limb discrepancy 11. experience of any orthotic treatments in knee joint or foot region 12. BMI more than 36 Kg/m<sup>2</sup> 13. hip joint or lumbar joints arthritis 14. hallux stiffness, midfoot valgus deformity, hindfoot arthropathy, foot ligament laxity, flat foot or any other problems that caused restriction for use of insole 15. knee joint valgus malalignment or knee joint recurvatum 16. problems which limited independent walking

**Age**

From **40 years** old to **54 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **23**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences, Rehabilitation school

**Street address**

Research committee, Rehabilitation School, Tehran University of Medical Sciences, Shahnazari St., Mirdamad Blvd.

**City**

Tehran

**Postal code****Approval date**

2010-11-02, 1389/08/11

**Ethics committee reference number**

265

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

Knee Osteoarthritis

**ICD-10 code**

M17.1

**ICD-10 code description**

primary gonarthrosis, Unilateral

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

Lateral Trunk lean angle

**Timepoint**

before using insole and immediately after using insole with and without subtalar strap

**Method of measurement**

6 camera Vicon Motion analysis system

**Secondary outcomes****1****Description**

walking speed

**Timepoint**

before using insole and immediately after using insole with and without subtalar strap

**Method of measurement**

Vicon motion analysis system with 6 cameras

**Intervention groups****1****Description**

Lateral wedge insole and subtalar strap with Gymnastic shoes

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

University of Welfare and Rehabilitation Sciences

**Full name of responsible person****Street address****City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice-chancellor for Research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr M. Moradi Lakeh

**Street address**

Vice-chancellor for Research, Tehran University of Medical Sciences

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for Research, Tehran 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**

Rehabilitation School, Tehran University of Medical Sciences

**Full name of responsible person**

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PhD of Orthotics and Prosthetics

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## Person responsible for scientific inquiries

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Master student of orthotics and prosthetics

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## Person responsible for updating data

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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*