

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of the lateral wedged insoles and knee orthoses on the knee dynamic valgus in people with patellofemoral pain syndrome

Protocol summary

Study aim

To investigate the effects of the lateral wedged insoles and knee orthoses on the knee dynamic valgus in people with patellofemoral pain syndrome

Design

A crossover study with 15 participants

Settings and conduct

Participants were recruited from outpatient clinics through a convenience sampling method.

Participants/Inclusion and exclusion criteria

Inclusion criteria were positive sign for " Patella Femoral Grinding test" and score more than three on visual analogue scale. Exclusion criteria included presence of a history of fracture and surgery in the lower limb and Instability of the knee due to trauma and other musculoskeletal disorders.

Intervention groups

Interventions were using lateral wedge insole, knee support, lateral wedge and knee support together.

Main outcome variables

The Main outcome measures were parameters of the gait pattern, valgus angle at the knee, and pain intensity during squat.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N4**

Registration date: **2020-01-07, 1398/10/17**

Registration timing: **retrospective**

Last update: **2020-01-07, 1398/10/17**

Update count: **0**

Registration date

2020-01-07, 1398/10/17

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2016-05-30, 1395/03/10

Trial completion date

2016-06-14, 1395/03/25

Scientific title

Effects of the lateral wedged insoles and knee orthoses on the knee dynamic valgus in people with patellofemoral pain syndrome

Public title

Orthosis and Insole for patellar pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Positive Patella Femoral Grinding test Score more than three on visual analogue scale Age over 18 years

Exclusion criteria:

The history of fracture and surgery in the lower limb

Instability of the knee due to trauma and other musculoskeletal disorders

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran

Street address

Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2015-09-27, 1394/07/05

Ethics committee reference number

IR.MUI.REC.1394.3.452

Health conditions studied

1

Description of health condition studied

Patellofemoral Pain Syndrom

ICD-10 code

M22.2X

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description

Perception of the pain intensity during squat on the affected limb

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

Participants were asked to indicate the intensity of the perceived pain on a 10 cm scale.

2

Description

Gait symmetry

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

Walking of participant was recorded using a motion capture system then parameters of the "gait symmetry" calculated and reported using a Visual 3D software.

3

Description

Speed of walking

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

Walking of participant was recorded using a motion capture system then parameters of the "walking velocity" calculated and reported using a Visual 3D software.

4

Description

Peak of the frontal moment at knee during gait

Timepoint

Peak of the frontal moment at knee during gait

Method of measurement

Walking of participant was recorded using a motion capture system then parameters of the "Peak frontal moment at the knee" calculated and reported using a Visual 3D software.

5

Description

Dynamic valgus angle during gait

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured.

Method of measurement

Walking of participant was recorded using a motion capture system then parameters of the "Dynamic valgus angle during gait" calculated and reported using a Visual 3D software.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lateral wedge insole. This was a full-length insole made from poly-Vinyl acetate. The inclination of the insole in the frontal plan was 8 degrees for the affected limb and zero for the sound limb.

Category

Treatment - Devices

2

Description

Intervention group: Knee support. This was a neoprene knee support that supports the knee with four bilateral stays. This knee support was selected and fitted according to circumstance measurement of the knee.

Category

Treatment - Devices

3

Description

Intervention group: Lateral wedge insole and knee support together. The lateral wedge and knee support was used together for participants.

Category

Treatment - Devices

4

Description

Control group: no orthosis. Participants completed the tests without lateral wedge or knee support.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Isfahan, Iran

Full name of responsible person

Khalilolah Nazem

Street address

Sofeh Blvd

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Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

Street address

Hezar Jerib St.

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۷۳۴۶۱-۸۱۷۴۶

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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

Ebrahim Sadeghi-Demneh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long

No specific limitation is considered.

To whom data/document is available

No limit was set.

Under which criteria data/document could be used

No terms and conditions is considered for sharing the data.

From where data/document is obtainable

People can send their request to the correspondence and obtain the data.

What processes are involved for a request to access data/document

Request can be sent through an email.

Comments