Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone
+98 31 3792 5235

Email address
sadeghi@rehab.mui.ac.ir

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

Isfehan

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
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alzahra@mui.ac.ir
Web page address
http://alzahra.mui.ac.ir

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.
City
Isfahan
Province
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Phone
+98 31 3668 5149
Email
research@mui.ac.ir
Web page address
http://research.mui.ac.ir/fa/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D9%BE%DA%98%D9%88%D9%87%D8%B4%DB%8C-%D9%88%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C
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
Street address
Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5235
Fax
+98 31 3668 7270
Email
sadeghi@rehab.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan 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
Street address
Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5235
Fax
+98 31 3668 7270
Email
sadeghi@rehab.mui.ac.ir

Person responsible for updating data

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
Street address
Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5235
Fax
+98 31 3668 7270
Email
sadeghi@rehab.mui.ac.ir

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 shred 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 sent 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