

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of custom-made foot orthoses on pain and function in subjects with lower back pain and flatfoot

Protocol summary

Summary

1) Objectives: Evaluation of effectiveness of custom-made foot orthoses for reducing pain and improving function in subjects with lower back pain and flatfoot 2) Study design: A randomized, single-blinded, control group with a placebo 3) Setting and conduct: Participants with flatfoot and chronic or recurrent low back pain will randomly allocate to two groups: treatment and control. Treatment group will treat with the custom-made foot orthoses, and control will treat with prefabricated orthoses. Low back pain was evaluated by a visual analog scale for pain and Oswestry's Disability Index Questionnaire for lower back pain at four moments—on the day of inclusion in the study and after 6,12 and 24 weeks of using the orthoses. 4) Participants: Subjects between 18-35 years old with chronic non-specific low back pain who have flatfoot will included and any pathologic or non-mechanical low back pain and previous use of foot orthoses will excluded. 5) Intervention: One pair custom-made foot orthoses for treatment group that after the foot scan, foot orthoses was made based of each subject's foot and was administered immediately after preparation. In control group one pair prefabricated orthoses was administered. 6) Main outcome: Low back pain which is evaluated by a visual analog scale(VAS) and function which is evaluated by Oswestry's Disability Index Questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015113025308N1**
Registration date: **2016-01-05, 1394/10/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-05, 1394/10/15

Registrant information

Name

Maryam Mirshahi

Name of organization / entity

Sina Specialized & Subspecialty Hospital, Teharn
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tehran University of Medical
Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of custom-made foot orthoses on pain and
function in subjects with lower back pain and flatfoot

Public title

The effect of custom-made foot orthoses on low back
pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: subjects between 18-45 years old with pain between T12 and the S1 joints: presence of chronic non-specific low back pain for at least 6 weeks or recurrent low back pain for 3 months: Foot Posture Index (FPI-6) indicating at least +6 Exclusion criteria: any pathologic or non-mechanical low back pain: history of foot surgery, foot or lower extremity trauma or other conditions that may affect the measurement of this study: previous use of orthoses: leg length discrepancy greater than 5 mm: peripheral neuropathy due to disorders such as diabetes

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods Aven., Keshavarz Blv., Tehran, Iran

City

Tehran

Postal code

Approval date

2015-11-25, 1394/09/04

Ethics committee reference number

IR.TUMS.REC.1394.1276

Health conditions studied

1

Description of health condition studied

Low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

level of pain

Timepoint

on the day of inclusion in the study, 6th week, 12th week, 24th week

Method of measurement

Visual Analogue Scale (VAS)

2

Description

level of function

Timepoint

on the day of inclusion in the study, 6th week, 12th week, 24th week

Method of measurement

Oswestry Disability Index Questionnaire

Secondary outcomes

1

Description

Foot pain

Timepoint

at first visit, then every 4 weeks

Method of measurement

Question of subjects

Intervention groups

1

Description

Control group: one pair prefabricated foot orthoses made with polyester adjusting in to the size of the foot and fitting it into the shoes without change base of the foot mold. Instructions were given to the patients for gradual wearing the foot orthoses to discomfort and after 2 weeks, at least, 8h/day.

Category

Other

2

Description

Intervention group: one pair custom-made foot orthoses made with polypropylene from heel to just behind the metatarsal heads. Instructions were given to the

participants for gradual wearing the foot orthoses to discomfort and after 2 weeks, at least, 8 h/day.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Medicine Clinic, Sina Specialized & Subspecialty Hospital

Full name of responsible person

Maryam Mirshahi, MD, Sports Medicine Specialist

Street address

Sina Hospital, Imam Khomeini Ave., Hassan Abad Sq., Tehran, Iran

City

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2

Recruitment center

Name of recruitment center

Sports and exercise department, Imam Khomeini Hospital

Full name of responsible person

Maryam Mirshahi, MD, Sports Medicine Specialist

Street address

Imam Khomeini Hospital, End of Keshavarz Blv, Tehran, Iran

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3

Recruitment center

Name of recruitment center

Sports Medicine Clinic, Sports Medicine Research Center

Full name of responsible person

Maryam Mirshahi, MD, Sports Medicine Specialist

Street address

No 7, Al-e-Ahmad Highway, Sports Medicine Research Center, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tehran University of Medical Sciences

Full name of responsible person

Masoud Yunesian, MD

Street address

Tehran university of Medical Science, Qods Aven., Keshavarz Blv., Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of 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

Sina Specialized & Subspecialty Hospital

Full name of responsible person

Maryam Mirshahi, MD

Position

Sports Medicine Specialist

Other areas of specialty/work

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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