

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of altered lumbar belt, with and without custom-made insoles, and comparison of it with common prefabricated belts on low back pain and functional disability in pronated foot patients.

Protocol summary

Study aim

to determine Effect of altered lumbar belt, with and without custom-made insoles, and comparison of it with prefabricated belts on low back pain and functional disability in pronated foot patients.

Design

This study is a randomized clinical trial. According to previous studies, considering the error of 5% (95% confidence interval) and power of 80%, and the effect size equal to 60%, a sample size of 9 people in each group is required (In total equivalent to 36 people). Due to the possibility of falling, the sample size will increase to 10 people in each group. Participants will be randomly assigned to one of the groups. For proper and random assignment in groups, block arrangement will be used according to Appendix 3.

Settings and conduct

Sampling is performed among patients referred to neurology and orthopedic clinics of Shahid Rajaei Hospital in Shiraz according to the inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

inclusion criteria: non-specific low back pain, pronation in one or both feet, Age between 30 to 50 years, chronic low back pain, minimum score of 3 on the VAS for low back pain at the start, Body mass index between 18.5 to 30
Non-entry conditions: History of injury or surgery on ankle or back, concomitant use of other treatments such as physiotherapy or injections, mobility impairment, lameness or Significant asymmetry in walking, pregnancy or history of labor in the last six months, anisomelia more than 5 mm, history of ankle sprain, rigid pronation, genovarum

Intervention groups

Control group: Tavanmehr prefabricated belt, 1st
intervention group: modified belt which is the same as conventional belt with silicone textured pad, 2nd

intervention group: computer scan insole, 3d
intervention group: modified belt with custom insole simultaneously

Main outcome variables

pain and disability in chronic low back pain with origin of foot pronation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220403054393N1**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **prospective**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

bahareh delshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

b.delshad20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-28, 1401/03/07

Expected recruitment end date

2022-11-28, 1401/09/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of altered lumbar belt, with and without custom-made insoles, and comparison of it with common prefabricated belts on low back pain and functional disability in pronated foot patients.

Public title
Effect of lumbar belt and custom-made insoles on low back pain and functional disability in pronated foot patients.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 nonspecific low back pain diagnosed by medical profession and checked by questionnaire 1 pronation in one or both feet (more than +6 score in FPI test age between 30 and 50 having at least score 3 for low back pain in VAS at the beginning of treatment BMI between 18.5 to 30
Exclusion criteria:
 History of injury or surgery on the foot or back
 Concomitant use of other treatments such as physiotherapy or injections to reduce pain and increase ability
 Positive answer to each of the questions in Appendix 1
 Any progressive or non-progressive mobility impairment with psychological, neurological, rheumatological and orthopedic reasons that overshadow the ability to participate and be effective in the study
 Specific lameness or asymmetry in walking
 Pregnancy or delivery history in the last six months
 anisomelia more than 5 mm
 history of ankle sprain
 rigid pronation in ankle genuvarum

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of each person to four groups with conventional belt, modified belt, custom insole and modified belt with custom insole will be done according to Appendix 3 block arrangement. For example, according to this list, the first participant will be set in the control group. The second participant in first intervention group, the third participant in third intervention, the fourth participant in second

intervention, and so on as the participants include. That is, the allocation sequence will be completely random and based on the randomized block method (arrangement available as a proposal attachment).

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of University of Social Welfare and Rehabilitation Sciences

Street address

Evin Daneshjoo Blvd., Koodkier St., University of Social Welfare and Rehabilitation Sciences

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.USWR.REC.1400.305

Health conditions studied

1

Description of health condition studied

chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

low back pain

Timepoint

at the beginning of study and 6 week later

Method of measurement

visual analog scale

2

Description

disability

Timepoint

at the beginning of study and 6 week later

Method of measurement

oswestry questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: common prefabricated belt. The belt from Tavanmehr Company is considered for each patient based on the recorded size of the pelvic environment in the area between the anterior superior iliac spine and the trochanter and will be closed above the pubice. The force applied by the belt will be 50 Newtons, which is measured by a tensile dynamometer. Then, based on this force, the correct closing place is marked and determined for the patient on the belt, and we ask him to fasten the belt in the same place, and in case of noticeable size or weight change, inform us to adjust the belt.

Category

Treatment - Devices

2

Description

first Intervention group: altered belt. It is the same as prefabricated belt in which a textured pad is embedded. This pad has a triangular pattern in the shape of a sacrum that covers the lumbar and sacral areas and will be made of silicone, which by installing small cylindrical villi with a height of one centimeter and a diameter of half a centimeter increases the sense of touch and thus proprioception in the lumbar region. Each of the villi will be placed at equal distances of two centimeters from each other. The pad will be attached to the prefabricated belts with Velcro double-sided adhesive. The force applied by the belt will be equal to 50 Newtons, which is measured by a tensile dynamometer.

Category

Treatment - Devices

3

Description

second Intervention group: custom made insole. Insole fabrication for each patient will be done exclusively by CAD-CAM method. For this purpose, using pressure scan PT-SCAN model 4452F40 of Payafnavaran Ferdowsi Company, made in Iran, pressure scan will be obtained from the participants. The obtained computer scan is evaluated separately for each patient and a special insole is designed for them using PT insole design

computer software. The medial edge is 4 degrees from the midline to the inner edge of the insole and is based on the size of the patient foot will be 6 to 8 mm long. The length of the medial longitudinal arch, depending on the size of the patient's foot and the size recorded for him from the talus bone to the head of the first metatarsus and its height will be 15 mm. The metatarsal pad will be located 5 mm behind the second to fourth metatarsals. The size of the metatarsal pad will be such that it covers the three central metatarsals. The height of the metatarsal pad gradually increases from the edges to the middle up to 6 mm at the midpoint. At the end, information is given through G-codes to the device related to Paya Fanavaran Company made in Iran, which cuts the insoles on the foam block with a thickness of 2/3 with the shore of 35 to 40.

Category

Treatment - Devices

4

Description

third Intervention group: altered belt and custom made insole. Both of these interventions are used simultaneously.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Dr. Seyed Reza Mousavi

Street address

Shahid Rajaei Hospital, before Niayesh Boulevard, Chamran Boulevard

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7194815711

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khankeh

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Bahareh Delshad

Position

PhD student

Latest degree

Master

Other areas of specialty/work

orthotics and prosthetics

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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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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total potential data after unidentifiable individuals according to the patient information form and file created for them.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific

institutions and people working in the profession

Under which criteria data/document could be used

To do research work and in coordination with the researcher

From where data/document is obtainable

Bahareh Delshad, E-mail b.delshad20@gmail.com

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

After consulting with other design partners and approving them, the data will be provided to the applicant

Comments

The applicant needs to clearly explain why the data is needed