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

+98 71 3627 4458

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 firs intervention group , the third participan 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., Koodkiar 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 begining of study and 6 week later

Method of measurement

visual analog scale

2

Description
disability
Timepoint
at the begining 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
City
Shiraz
Province
Fars
Postal code
7194815711
Phone
+98 71 3636 4001
Email
rajaeehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamidreza Khankeh
Street address
University of Rehabilitation Sciences and Social

Health, Koodkiar St., Evin Daneshjoo Blvd.

City
تهران

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0083

Email
vcrdep@sums.ac.ir

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

Street address
Unit 3, in front of Alborz Taxi, Valiasr St., Qasr Al-Dasht St.

City
شیراز

Province
Fars

Postal code
7183813455

Phone
+98 71 3627 4458

Email
b.delshad20@gmail.com

Person responsible for scientific 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
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Postal code
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Phone
+98 71 3627 4458

Email
b.delshad20@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Bahareh Delshad

Position
PhD student

Latest degree
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Email
b.delshad20@gmail.com

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