Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparision between puzzle insole and conventional four-layer insole with offloading rocker sole shoe on dynamic balance and spatio-temporal parameters of gait in patients with diabetic foot ulcers

Protocol summary

Study aim
Comparision of the effect of puzzle insole and conventional four-layer insole with offloading rocker sole shoe on dynamic balance and spatio-temporal parameters of gait in patients with diabetic foot ulcers

Design
A crossover clinical trial in which each person receives three interventions.

Settings and conduct
Balance and time-spatial parameters of gait test will be done with systematic analysis treadmill at Tehran Sport Sciences Research Institute

Participants/Inclusion and exclusion criteria
Inclusion criteria: Shallow diabetic plantar ulcer in the forefoot in patients 40 to 60 years old who do not have a history of balance disorders or a history of taking medications affecting balance. Exclusion criteria: patient's disinclination to cooperate or inability to walk

Intervention groups
Intervention 1:puzzle insole in offloading 20 rocker sole shoes Intervention 2:conventional four-layer insole in offloading 20 rocker sole shoes Intervention 3:control: the patient's own shoes, which are low top with flat insoles

Main outcome variables
Step length, step width, number of steps, step time, percentage of stance phase time, mid-stance phase time percentage, anterior-posterior shift of the center of pressure, lateral shift of the center of pressure, standard deviation of the center of pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240405061417N1**
Registration date: **2024-08-06, 1403/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-06, 1403/05/16**
Update count: **0**

Registration date
2024-08-06, 1403/05/16

Registrant information

Name
AKRAM TADI BENI

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date
2024-08-20, 1403/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision between puzzle insole and conventional four-layer insole with offloading rocker sole shoe on dynamic balance and spatio-temporal parameters of gait in patients with diabetic foot ulcers

Public title
Comparison of the effect of two types of offloading insoles on the balance of patients with diabetic foot ulcers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic patients with foot ulcers only due to neuropathy The ulcer of the forefoot The maximum size of the ulcer is 2x2 cmm The age of patients should be between 40 and 60 years Diabetic foot ulcer is shallow No amputation of fingers Absence of disease due to imbalance such as Parkinson's, MS, vestibular disorders or similar cases Not taking drugs that affect balance Have no history of using the researched off-loading shoes
Exclusion criteria:
The ulcer is on the foot or leg or in the hindfoot The vascular ulcers or neurovascular ulcers The ulcer has involved the bone
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **3**
The balance test for each participant will be done once with the patient's own shoes, once with off-loading shoes with 20-degree rocker sole and conventional four-layer soles, and once with off-loading shoes with 20-degree rocker sole and four-layer puzzle soles.
Randomization (investigator's opinion)
Randomized
Randomization description
In this cross-over study, the sequence of interventions and experimental conditions will be randomly determined as follows: First, a list of all participants will be prepared. Then, a random number generation software will be utilized to determine the sequential order for each participant. For this purpose, randomization algorithms available in R software will be used. Each participant will be assigned a unique random number that specifies the order of interventions and experimental conditions. The process will involve assigning even numbers to one order and odd numbers to another. The results of the random assignment will be documented in separate tables, and the final order for each participant will remain confidential, with no review by other researchers, to ensure fair and random allocation.
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
Ethics committee of Iran University of Medical Sciences
Street address
Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Shah Nazari St., Maddkaran St., Mader Square, Mirdamad, Tehran
City
Tehran
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Tehran
Postal code
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Approval date
2023-07-31, 1402/05/09
Ethics committee reference number
IR.IUMS.REC.1402.375

Health conditions studied

1

Description of health condition studied
Diabetic polyneuropathy
ICD-10 code
G63.2
ICD-10 code description
Diabetic polyneuropathy

Primary outcomes

1

Description
Step width: It means the distance between the line of progress of the left foot and the line of progress of the right foot
Timepoint
Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole.
Method of measurement
In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

2

Description

Step legnth: The length measured parallel to the forward line of the body from the heel contact of one foot to the heel contact of the other foot

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole.

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

3

Description

Step time: The time interval between the heel contact of one foot with the ground and the heel contact of the opposite foot with the ground

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole.

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

4

Description

Stance time percentage :This phase starts when the foot is in contact with the ground and with the complete separation of the same foot from the groundIt ends. The stance phase constitutes approximately 60% of the walking phase

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

5

Description

The time percentage of the midstance phase: in observation; This phase of walking starts with the separation of the toes of the opposite foot from the ground and continues until the heel of the progressive foot is in contact with the ground and accounts for 29 to 37% of walking

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

6

Description

The number of steps per unit of time (cadence): is the frequency of steps

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

7

Description

Lateral shift of the center of pressure: indicating the movement direction of the center of pressure to the left and right

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

8

Description

Anterior-posterior shift of the center of pressure: the direction of movement of the center of pressure is anterior-posterior

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker sole with a puzzle insole

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

9

Description

Standard deviation of the center of pressure: The standard deviation of the center of pressure is obtained by calculating the displacement of all steps

Timepoint

Along with the patient's own shoes. After wearing shoes with a 20 degree rocker sole with a conventional four-layer insole. After wearing shoes with a 20 degree rocker

sole with a puzzle insole

Method of measurement

In this study will be measured by Treadmill device for systematic analysis of walking and running, and will be calculated and recorded with T-FDM zebris software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: offloading shoes with a 20-degree rocker sole with a conventional four-layer insole. Rocker insole shoe is a type of footwear modification where the sole of the shoe is curved. Its purpose is to allow the body's center of mass to roll over the support surface. The conventional four-layer insole used in this research consists of an upper layer of plastazote with a hardness of A30 in contact with the foot, a polyethylene foam layer with a hardness of A40 as the second layer, a polyethylene foam layer with a hardness of A50 as the third layer, and a shear force reduction layer made of pron located underneath all the layers.

Category

Rehabilitation

2

Description

Intervention group: offloading shoes with a 20-degree rocker sole with a puzzle four-layer insole. Rocker insole shoe is a type of footwear modification where the sole of the shoe is curved. Its purpose is to allow the body's center of mass to roll over the support surface. The conventional four-layer insole used in this research consists of an upper layer of plastazote with a hardness of A30 in contact with the foot, a polyethylene foam layer with a hardness of A40 as the second layer, a polyethylene foam layer with a hardness of A50 as the third layer, and a shear force reduction layer made of pron located underneath all the layers.

Category

Rehabilitation

3

Description

Control group: The patient's own shoes, which are low top with flat insoles

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

IUMS School of Rehabilitation Science

Full name of responsible person

Dr Hasan Saeedi

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Akram Tadi Beni
Position
Masters student
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable