

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Determining the critical threshold of plantar pressure in diabetic people with healed wounds in Tehran and determining the elastographic characteristics of the plantar tissue of these patients following the use of customized insoles

Protocol summary

Study aim

Determining the critical threshold of plantar pressure in people with diabetes with healed plantar ulcer in Tehran

Design

In the first phase, a group of 150 people was selected, and after determining the pressure threshold, in the second phase, 30 people were selected to make insoles, and in the third phase, after using the insoles, elastography was performed again.

Settings and conduct

This study is in 3 phases, in the first step, sampling with the available method and selecting 150 people and collecting information about plantar pressure using the Pedar device, in the second step, making medical insoles based on the offload of high pressure points, and in the last step, using the elastography technique, on 30 people before and after medical insole intervention.

Participants/Inclusion and exclusion criteria

Diabetic neuropathic patients of both sexes, aged between 30 and 80 years, with a history of ulcers in the toe area, which is at least 90 days from complete recovery and the ability to walk without assistance, and people with amputations in the lower limbs or ulcers in the soles of the feet and restrictions Mobility of lower limb joints and having Charcot arthropathy or peripheral vascular diseases and history of lower limb surgery are excluded from the study.

Intervention groups

Custom-made and offload at points where the pressure is high

Main outcome variables

Predicting points with high risk of ulcers, preventing recurrence of ulcers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049687N4**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Alireza Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5053

Email address

taheri@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2025-03-15, 1403/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the critical threshold of plantar pressure in diabetic people with healed wounds in Tehran and determining the elastographic characteristics of the plantar tissue of these patients following the use of customized insoles

Public title

Investigating the critical threshold of plantar pressure in people with diabetes with healed wounds

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

neuropathic diabetic people of of tehran city of both genders aged 30 to 80 years old Ability to read, write and understand Farsi People with a history of wound in forefoot that has been fully healed for at least 90 days Ability to walk independently without needing Assistance the ability to walk and stand without the use of assistive devices

Exclusion criteria:

The presence of any type of amputation in the lower limb or the presence of any wound on the sole of the foot Movement limitation of lower limb joints (ankle, knee and hip) which cause instability in standing and walking Charcot arthropathy condition. Peripheral vascular diseases A history of surgery in the back or lower limbs during the last six months or accompanying diseases that cause movement restriction and instability while walking

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

school rehabilitation , hezajirib St., Isfahan Town

City

Isfahan

Province

Isfahan

Postal code

8074673461

Approval date

2023-11-29, 1402/09/08

Ethics committee reference number

IR.MUI.REC.1402.032

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Prediction of points with high risk of wound

Timepoint

Measurement of blood pressure threshold at the beginning of the study (before the start of the intervention) and one month after the intervention

Method of measurement

plantar pressure measurement device (pedar) and sole skin firmness device (elastography)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After determining the sole pressure threshold, in the next step, the firmness of the skin of the soles is determined with the elastography device, and a number of people are selected to make insoles and shoes, and after using the insoles and shoes, elastography will be performed again.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar Diabetes Center

Full name of responsible person

Alireza Taheri

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School rehabilitation, Hezajirib St., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Proportion provided by this source

60

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

alireza taheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Orthosis and prosthesis

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

alireza taheri

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying people, also part of the data related to the main outcome can be shared.

When the data will become available and for how long

The access period starts one year after the results are published

To whom data/document is available

The data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Specialists in the field of orthotics and prosthetics and diabetes can receive the data after requesting and diagnosing the correct use

From where data/document is obtainable

Applicants should only refer to the email address

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

After sending the request to my email and reviewing the request, a response will be sent within 15 days

Comments