

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of foot position on tissue oxygenation in diabetic foot ulcers

Protocol summary

Study aim

Determining the effect of foot position on tissue oxygenation (TCPO₂) in diabetic foot ulcers

Design

A randomized controlled clinical trial, conducted on 60 patients with diabetic foot ulcers, will be conducted using Python using the Permutation and Random library.

Settings and conduct

This study was conducted in the surgical department of 4 Velayat Hospital affiliated with Mashhad University of Medical Sciences and demographic information, transcutaneous oxygen tension values, limb pressure, and ankle and calf circumferences were measured. Then, in the intervention group, the patient's leg will be elevated 15 degrees from the bed surface by measuring with a goniometer and placed on a pillow for 24 hours. In the control group, the leg with the ulcer will be placed on the bed surface in a supine position for 24 hours. In both groups, the calf and ankle circumferences were measured twice before and during the intervention, and transcutaneous oxygen tension values were measured and recorded by the nurse caring for the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic foot ulcers (arterial ulcers) with grades 2C, 2D, 3C and 3D based on the Texas criteria and without any therapeutic intervention and care in the inpatient ward - No history of disease such as epilepsy, cognitive disorders, orthopedic, cardiovascular problems, infection, amputation - No contraindications to foot positioning Exclusion criteria: Failure to comply with the treatment protocol including foot positioning for more than two hours

Intervention groups

Intervention group (foot elevation): The ulcerated foot in patients in this group will be placed at a height of 15 degrees above the heart level for 24 hours. Control group (foot supine): The ulcerated foot will be placed on the bed surface for 24 hours.

Main outcome variables

Transcutaneous oxygen pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241223064142N1**

Registration date: **2025-01-03, 1403/10/14**

Registration timing: **prospective**

Last update: **2025-01-03, 1403/10/14**

Update count: **0**

Registration date

2025-01-03, 1403/10/14

Registrant information

Name

Fatemeh Khani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3760 5532

Email address

fatemehkhani4401@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-04-22, 1404/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of foot position on tissue oxygenation in diabetic foot ulcers

Public title

The effect of foot position on tissue oxygenation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic foot ulcers with grades 2C, 2D, 3C, and 3D based on the Texas criteria Has an arterial ulcer (neuroischemic) without any therapeutic intervention or care in the inpatient ward No medical contraindication to participate in the study No restrictions on foot positioning Absence of diseases such as epilepsy and cognitive disorders, orthopedic, cardiovascular problems, infection, amputation

Exclusion criteria:

Changing the patient's position to a position that is not in line with the study objectives. If the patient is not in the study position for more than two hours.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment will be done with Python version 3 using the permutations and random libraries. These two libraries will be used to generate random sequences using the block generation method (here, blocks of 4 and 2 are used, which will be randomly generated and will randomly generate the sequence).

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

Faculty of Nursing and Midwifery -Mashhad University of Medical Sciences

Street address

Mashhad, Azadi Square, Mashhad University of Medical Sciences, Faculty of Medicine, First Floor

City

mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2024-12-28, 1403/10/08

Ethics committee reference number

IR.MUMS.NURSE.REC.1403.077

Health conditions studied

1

Description of health condition studied

Ulcer of lower limb, not elsewhere classified

ICD-10 code

L97

ICD-10 code description

Non-pressure chronic ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description

Transcutaneous oxygen pressure

Timepoint

Transcutaneous oxygen pressure measurement before the start of the intervention and 24 hours after the start of the intervention

Method of measurement

In the present study, transcutaneous oxygen pressure measurement was used via a touch screen monitor and a single-channel probe manufactured by Medicap, Germany.

2

Description

Calf circumference

Timepoint

Calf circumference measurement before the start of the intervention and twice during the 24-hour intervention

Method of measurement

Measuring calf circumference with a standard tape measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The ulcerated leg in patients in this group will be placed on a pillow at an elevation of 15 degrees above the heart level for 24 hours.

Category

Treatment - Other

2

Description

Control group: The ulcerated leg in patients in this group will be placed on the bed surface for 24 hours.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Gholamhossein Kazemzadeh

Street address

Intersection of Namaz Boulevard and Shahid Kaveh Boulevard, Velayat Hospital, Mashhad City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah Street, next to Hoveyze Cinema, University of Medical Sciences, Third Floor, Vice Chancellor for Research and Technology of the University, Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Khani

Position

Master's degree student in nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahdieh Arian Yeganeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be 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

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

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