Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 51 3760 5532

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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
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Daneshgah Street, next to Hoveyzeh 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
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Position
Professor
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Person responsible for updating data

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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