# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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)

**Phone**
+98 51 3760 5532

**Email address**
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**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 Hoveyzeh Cinema, University of Medical Sciences, Third Floor, Vice Chancellor for Research and Technology of the University,Mashhad
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vcresearch@mums.ac.ir
**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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**Full name of responsible person**
Mahdieh Arian Yeganeh
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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