

# 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 (TCPO<sub>2</sub>) 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

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

917789001

##### Phone

+98 51 3804 2000

##### Email

khazemzadegh@mums.ac.ir

## 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

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

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

##### Street address

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

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##### Phone

+98 51 3804 2000

##### Email

khaniF4012@mums.ac.ir

## 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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Ariyanm@mums.ac.ir

**Person responsible for updating data****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

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**Email**

khaniF4012@mums.ac.ir

**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