Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study Of the Effect of Topical Oxygen Therapy on Diabetic Foot Ulcer

Protocol summary

Study aim

The aim of this study was to determine the effect of topical oxygen therapy in diabetic foot ulcer patients in order to increase the quality of nursing care and improve the satisfaction of patients with diabetic foot ulcers in Qazvin University of Medical Sciences affiliated hospitals.

Design

Patients were randomly divided into two intervention and control groups. In the control group, only daily care, including regular care (dressing twice per shift), was performed, such as daily washing with normal saline and then with sterile gas And will be done with common dressing products and in the intervention group, in addition to the above-mentioned care, daily by catheter, 10 liters per minute flow of oxygen for 20 minutes three times a day for at least one week (or clearance time) at a distance of one centimeter wound will be rotated. The condition of the ulcer will be examined by the test cavity before and every 48 hours after the intervention for at least one week and (or until discharge)

Settings and conduct

This study is a randomized controlled trial with a representative sample of 40 patients admitted to the surgical ward of diabetic foot ulcer grade 2 and more in teaching hospitals affiliated to Qazvin University of Medical Sciences(VElayat and Buali Sina)

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patient's or CARE GIVER's consent
Exclusion criteria: Specific vascular injury such as buerger disease

Intervention groups

In the intervention group, the ulcer was first washed three times with sterile normal saline and then topically extruded with a high pressure of 10 liters per minute for 20 minutes. This is done three times a day

Main outcome variables

ULCER AREA-PAIN

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044148N1**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name
Alireza Salmani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study Of the Effect of Topical Oxygen Therapy on

Diabetic Foot Ulcer

Public title
The Effect of Oxygen on Diabetic Foot Ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ankle Brachial Index at Least 0.6 Patient's Personal consent or Companion Patient
Exclusion criteria:
Specific Vascular Injury Such as Buerger Disease
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this Study, Kevin Tosing method and simple random assigment method (using red and blue balls, the red ball representing the control group and the blue balloon representing the intervention group) will be used.
Blinding (investigator's opinion)
Single blinded
Blinding description
Intervention will take place on both day and day and on shifts in the morning and evening. Patients or their families were unaware of the intervention, so this is a one-blind study
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
QAZVIN UNIVERSITY MEDICAL OF SCIEMCE
City
QAZVIN
Province
Qazvin
Postal code
3414638588
Approval date
2019-07-01, 1398/04/10
Ethics committee reference number
IR.QUMS.REC.1397.395

Health conditions studied

1

Description of health condition studied
DIABETIC FOOT ULCER
ICD-10 code
E13
ICD-10 code description
Other specified diabetes mellitus

Primary outcomes

1

Description
FOOT ULCER AREA
Timepoint
Before and every 48 hours after the intervention for at least one week and (or until discharge
Method of measurement
The measurements are sterilized with Absalung

2

Description
PAIN OF DIABETIC FOOT ULCER
Timepoint
Before AND POST INTERVENTION
Method of measurement
VISUAL ANALOG SCALE

3

Description
Stress
Timepoint
Before intervention
Method of measurement
cohen perceived stress scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, the ulcer was washed three times with sterile normal saline, and then a high pressure oxygenated portion of 10 liters per minute was placed on the document for 20 minutes. At last, the wound was dressed with enough gas. This case is repeated three times a day.Document for 20 minute:

Based on the study by Eric Blackman et al. (2010), a study of treatment of severe diabetic foot ulcers with topical oxygen: a prospective controlled study at the Ontario Wound Center Clinic in Canada on 28 diabetic patients who had two The intervention and control groups were divided into two groups of silver bandages at least twice a week and in the intervention group 60 minutes of oxygen daily with topical wound treatment oxygen therapy (TWO2) given for 90 days from Monday to Friday. Were treated. Therefore, treatment was performed in 60 minutes and in three alternating 20 minute periods.

Category

Treatment - Other

2

Description

Control group: At first, the wound was closed three times with a normal saline serum, then with a sterile dry gel and then, depending on the size of the wound, with one or more dry sterilized gases.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bou Ali Sina Hospital

Full name of responsible person

DOCTOR MOHAMMAD ALI ZOHAL

Street address

Bu-Ali Sina Hospital, Qazvin- Bou-Ali Avenue,QAZVIN

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2

Recruitment center

Name of recruitment center

VELAYAT HOSPITAL

Full name of responsible person

DOCTOR ALI AKBAR KARAMI

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin 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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

DOCTOR JALIL AZIMIAN

Position

PHD OF NURSING

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
EMPTY
When the data will become available and for how long
EMPTY
To whom data/document is available
EMPTY
Under which criteria data/document could be used
EMPTY
From where data/document is obtainable
EMPTY
What processes are involved for a request to access data/document
EMPTY
Comments