

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Vacuum-Assisted Closure therapy versus Conventional Dressing in the management of Diabetic Foot Ulcer

Protocol summary

Study aim

Comparison between Negative-Pressure Wound Therapy and Conventional Dressing Therapy in Healing Patients with Infected Diabetic Foot Ulcer

Design

patients were randomly assigned to the study groups. Based on the Bland-Altman plot [and similar studies], 30 patients were assigned to each of the intervention and control groups

Settings and conduct

This RCT was conducted on all patients admitted to Modarres Hospital, Tehran, Iran in 2018 or 2019 who have been diagnosed with infected DFU.

Participants/Inclusion and exclusion criteria

diabetic patients with DFU in Modarres Hospital, Tehran, Iran between 2018- 2019 : Patients with vascular diseases, coagulopathies, non-debrided wounds, sepsis, some inabilities, and those who were unwilling to participate in the study were excluded.

Intervention groups

After matching the patients for age and gender, they were randomly assigned to the Vacuum-Assisted Dressing (VAC) and the Silver Sulfadiazine Ointment Dressing groups. The intervention started immediately after the surgical debridement. Wagner's grading system was used to classify the ulcers based on their surface and depth. The exact date and time of each debridement procedure was recorded to calculate the healing time. In the VAC group, the dressings were changed every 48 hours; however, in the control group, they were changed twice a day. The patients were followed up until the wounds were closed. The healing times, the wounds' surface areas, along with demographic information of patients, as well as possible complications were recorded in a checklist.

Main outcome variables

Healing speed :DFU-related complications :The ulcer size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160803029181N6**

Registration date: **2019-10-01, 1398/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-01, 1398/07/09**

Update count: **0**

Registration date

2019-10-01, 1398/07/09

Registrant information

Name

Nasser Malekpour Alamdari

Name of organization / entity

Shaid Behesht University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Vacuum-Assisted Closure therapy versus Conventional Dressing in the management of Diabetic Foot Ulcer

Public title

Efficacy of Vacuum-Assisted Closure therapy versus Conventional Dressing in the management of Diabetic Foot Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

diabetic patients with infected DFU.

Exclusion criteria:

vascular diseases coagulopathies non-debrided wounds sepsis some inabilities those who were unwilling to participate in the study

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

After matching the patients for age and gender, they were randomly assigned to the Vacuum-Assisted Dressing (VAC) and the Silver Sulfadiazine Ointment Dressing groups.

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**

Ethics commity of Shahid Beheshti University of Medical Sciences

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Daneshju Avenue Velenjak

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Postal code

1985717443

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SBMU.MSP.REC.1398.089

Health conditions studied**1****Description of health condition studied**

infected diabetes mellitus with foot ulcer

ICD-10 code

L97

ICD-10 code description

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

Primary outcomes**1****Description**

efficacy of dressing with negative pressure

Timepoint

From the initial debridement to the wound healing

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups**1****Description**

intervention group: treatment with negative pressure dressing will be done.

Category

Treatment - Devices

2**Description**

Control group: dressing with silver sulfadiazine ointment will be done.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Modarres Hospital

Full name of responsible person

Nasser Malekpour

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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Vascular Surgeon Fellowship
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available