Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Name of organization / entity
Shaid Behesht University of Medical Sciences
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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 Medicasl Sciences
Street address
Daneshju Avenue Velenjak
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Province
Tehran
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
Street address

Modarres Hospital;Kaj Sq;Saadat Abad;

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Full name of responsible person
Nasser Malekpour Alamdari

Position
Vascular Surgeon Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Latest degree
Subspecialist

Other areas of specialty/work
Vascular&laparoscopy

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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