

# 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)

##### Phone

+98 21 2207 4089

##### Email address

nassermalekpour@sbmu.ac.ir

##### 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

**Street address**

Daneshju Avenue Velenjak

**City**

Tehran

**Province**

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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

**Street address**

Modarres Hospital;Kaj Sq;Saadat Abad;  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Seyyed Ali Ziai  
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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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## Person responsible for scientific inquiries

#### Contact

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**Position**  
Associate professor  
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Subspecialist  
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Vascular&laparoscopy  
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## Person responsible for updating data

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Associate professor  
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**Other areas of specialty/work**  
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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