Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between negative pressure wound therapy versus standard wound care in diabetic foot patients at a tertiary care hospital

Protocol summary

Study aim
To compare the effectivity of negative pressure wound therapy (NPWT) versus standard modern wound care with moist dressings for treatment of diabetic ulcers in patients with type-II diabetes presenting to a tertiary care hospital.

Design
Two arm parallel group, randomized controlled trial with blinded outcome assessment of 190 total patients assessed for 12 weeks post treatment

Settings and conduct
Since procedural limitations did not allow blinding during the study, the endpoint of wound healing and size regression was assessed by an independent team of 3 consultants who were given the final results of the wounds in pictorial form to give their opinion of the changes before and after treatment and debridement. Both the assessors and the final analysis consultant was unaware of this double blinded study protocol

Participants/Inclusion and exclusion criteria
We made two groups of 95 patients each, one to receive standard dressing care and one to receive NPWT Inclusion criteria included all patients >18 years diagnosed clinically and blood sugar fasting and 2-hour-post prandial investigations in the diabetic range according to the (World Health Organization) WHO criteria presenting with a diabetic foot wound of more than 4 weeks duration corresponding to Wagner grade 2 for debridement. Exclusion criteria included patients with pregnancy, non-compliant to follow-up, necrotic tissue on ulcer with eschar that could not be debrided, malignancy, advanced cardiac and respiratory disease, exposed nerve and vessels beneath the ulcer

Intervention groups
Patients in Group N received NPWT (negative pressure wound therapy). Patients in Group S received standard modern moist wound dressing after debridement

Main outcome variables
Wound closure frequency, wound closure mean time, incidence of infection and amputation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231201060234N2**
Registration date: **2024-07-08, 1403/04/18**
Registration timing: **retrospective**

Last update: **2024-07-08, 1403/04/18**
Update count: **0**

Registration date
2024-07-08, 1403/04/18

Registrant information

Name
Rashid Ali

Name of organization / entity
Bolan medical college quetta

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-01, 1401/10/11

Expected recruitment end date
2023-06-30, 1402/04/09

Actual recruitment start date
2023-01-01, 1401/10/11

Actual recruitment end date
2023-06-30, 1402/04/09

Trial completion date
2023-06-30, 1402/04/09

Scientific title
Comparison between negative pressure wound therapy versus standard wound care in diabetic foot patients at a tertiary care hospital

Public title
Negative pressure versus standard wound therapy for diabetic foot

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Included all patients >18 years diagnosed clinically and BSF and 2-hour-post prandial investigations in the diabetic range according to the WHO criteria Presenting with a diabetic foot wound of more than 4 weeks duration corresponding to Wagner grade 2 for debridement.

Exclusion criteria:
Included patients < 18 years Pregnancy Non-compliant to follow-up Necrotic tissue on ulcer with eschar that could not be debrided Malignancy, advanced cardiac and respiratory disease Exposed nerve and vessels beneath the ulcer and patient with above ankle ulcer and those with Charcot arthropathy.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **160**
Actual sample size reached: **190**

Randomization (investigator's opinion)
Randomized

Randomization description
We made two groups of 95 patients each, one to receive standard dressing care and one to receive NPWT randomized through non-probability consecutive sampling via lottery method according to the inclusion criteria furnished. Simple randomization was done. Allocation concealment was carried out through envelopes and residents unaware of the study protocol

Blinding (investigator's opinion)
Double blinded

Blinding description
Since procedural limitations did not allow blinding during the study, the endpoint of wound healing and size regression was assessed by an independent team of 3 consultants who were given the final results of the wounds in pictorial form to give their opinion of the changes before and after treatment and debridement. Data analysis consultant was also blinded to the study protocol with data given as Group N and Group S

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical review board CMH Peshawar

Street address
CMH Road

City
Peshawar

Postal code
25000

Approval date
2022-12-22, 1401/10/01

Ethics committee reference number
CMH-PSC-004356

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcers

ICD-10 code
Z86.31

ICD-10 code description
Personal history of diabetic foot ulcer

Primary outcomes

1

Description
Mean wound closure time

Timepoint
During or after 12 weeks of therapy

Method of measurement
Subjective assessment by 3 consultants

Secondary outcomes

1

Description
Median pain scores

Timepoint
After 12 weeks of therapy

Method of measurement
Standard Visual Analog Scale for pain and Likert scale for satisfaction

2

Description
Incidence of infection
Timepoint
During 12 weeks of therapy
Method of measurement
Subjective by 3 independent consultants

Intervention groups

1

Description
Intervention group: Negative pressure wound therapy group (NPWT) (n=95) Patients in Group N received NPWT after debridement on admission in the hospital and were followed up for 12 weeks to assess for complete healing with 100% epithelization and fit for surgical closure. A standard sub-atmospheric pressure of 120 mmHg was applied on the debrided ulcer through a sealed wound attached to a suction pump. Patients were followed up for up to 12 weeks and primary and secondary variables noted by an independent surgical consultant unaware of the study protocol.
Category
Treatment - Other

2

Description
Intervention group: Standard moist wound therapy group (n=95) Patients in Group S received standard modern moist wound dressing after debridement and followed up for the same after complete epithelization and tissue formation for up to 12 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
CMH Peshawar
Full name of responsible person
Dr. Rashid
Street address
CMH Road
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
None
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
CMH Peshawar
Proportion provided by this source
1
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
CMH Rwp
Full name of responsible person
Rashid Ali
Position
PG Gen surgery
Latest degree
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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
The word file along with SPSS data set and output sheet would be shared once the article gets accepted and published

When the data will become available and for how long
Will be available after manuscript approval and would be able to download and use for five years

To whom data/document is available
only for academic purposes

Under which criteria data/document could be used
will be provided after official approval from primary author through email and link would be sent to download the data set from online backup repository

From where data/document is obtainable
Application to access data through official email of the primary author provided in the trial

What processes are involved for a request to access data/document
will be provided after official approval from primary author through email and link would be sent to download the data set from online backup repository total time would be 7-10 working days

Comments