

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Pakistan

Phone

+92 81 2850639

Email address

rashid_zahidbaloch@hotmail.com

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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Phone

+92 333 3384051

Email

rashid_zahidbaloch@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CMH Peshawar

Full name of responsible person

Dr Rashid Baloch

Street address

CMH Road

City

Peshawar

Postal code

25000

Phone

+92 333 3384051

Email

rashid_zahidbaloch@hotmail.com

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

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

CMH Rwp

Full name of responsible person

Rashid Ali

Position

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Person responsible for updating data

Contact

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Full name of responsible person

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Fax**Email**

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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