

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 analyster

**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

##### City

Peshawar

##### Postal code

25000

##### 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

##### Street address

D7

##### City

Rawalpindi

##### Province

Punjab

##### Postal code

46000

##### Phone

+92 81 2850639

##### Fax

##### Email

Rashid\_zahidbaloch@hotmail.com

## Person responsible for scientific 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

**Street address**

D7

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 81 2850639

**Fax****Email**

Rashid\_zahidbaloch@hotmail.com

## Person responsible for updating data

### 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

**Street address**

D7

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 81 2850639

**Fax****Email**

Rashid\_zahidbaloch@hotmail.com

## 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**