STUDY PROTOCOL

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Official Title:

Comparison of outcome of mean duration of wound healing between vacuum assisted closure (VAC) versus conventional dressings for the treatment of wounds in patients

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1. Official Title

Comparison of outcome of mean duration of wound healing between vacuum assisted closure (VAC) versus conventional dressings for the treatment of wounds in patients

2. Background and Rationale

Open contaminated and dirty wounds are common surgical problems. Vacuum-assisted closure (VAC) therapy is used to promote granulation tissue formation, remove exudate and support wound healing. Conventional saline-moistened dressings remain a standard method of wound care. This study will compare the mean duration of wound healing between VAC therapy and conventional dressings in eligible patients.

3. Objective

To compare the outcome of mean duration of wound healing between vacuum assisted closure (VAC) versus conventional dressings for the treatment of wounds in patients.

4. Hypothesis

Null Hypothesis: There is no difference in outcome in terms of mean healing time following vacuum assisted closure technique versus conventional dressings for the treatment of wounds.

Alternative Hypothesis: There is difference in outcome in terms of mean healing time following vacuum assisted closure technique versus conventional dressings for the treatment of wounds.

5. Study Design

Randomized controlled trial.

6. Study Setting

Department of General Surgery, Jinnah Postgraduate Medical Centre (JPMC), Karachi.

7. Study Duration

Six months after the approval of synopsis from CPSP.

8. Sampling Technique

Non-probability consecutive sampling.

9. Sample Size

OpenEpi calculator was used to calculate the sample size by taking the mean healing time in Group A (9.83 ± 1.32 days) and Group B (16.30 ± 1.37 days), level of significance 5% and power of study 80%. The estimated sample size was 24 patients, 12 in each group. The study will include 30 patients in each group to increase the strength of data.

10. Inclusion Criteria

Patients having open contaminated and dirty wounds of size 5–10 cm as per operational definition.

Patients between ages 15 to 60 years.

Both genders.

ASA grade I and II.

Willing to provide written informed consent.

11. Exclusion Criteria

Patients with wounds having dry eschar, malignancy in wound, untreated osteomyelitis, exposed blood vessels and organs, long-term anticoagulant therapy, bleeding disorders and fistula to organ/body cavities. Dermatological disorders like acute dermatitis and fungal infections of perianal region.

All patients with exposed bone, tendons or nerve will be excluded.

Pregnant women.

Patients on medications such as corticosteroids, immunosuppressive agents or chemotherapy.

12. Randomization and Interventions

All eligible patients will be randomly divided into two groups by lottery method. Group A will undergo vacuum assisted closure technique and Group B will undergo conventional dressings.

All wounds will be washed thoroughly with normal saline and debridement will be done if needed.

Group A: The wound will be covered with polyurethane foam and a multi-hole drain will be placed over it, then sealed with airtight dressing. The drain will be attached to a negative pressure system providing intermittent negative pressure of 125 mmHg with 45 minutes ON and 15 minutes OFF cycle. Dressing will be changed after 48–72 hours.

Group B: A saline-soaked dressing will be placed over the wound and bandage applied. Dressing will be changed every 24 hours.

13. Follow-up and Outcome Assessment

Patients in both groups will be observed for a maximum of two weeks. Improvement in wound granulation will be noted. VAC therapy will be discontinued when the aim of therapy is met or if there is no improvement in wound after 3–4 applications. Duration of wound healing will be recorded in days and wound surface area will be measured in cm^2. All patients will be assessed by the researcher.

14. Primary Outcome

Mean duration of wound healing in days.

15. Data Collection

Patients will be admitted from the outpatient and emergency departments after meeting the inclusion criteria. The purpose and procedure of the study will be explained and written informed consent will be obtained. Demographic data including age, gender, ASA grade, wound size and site of wound will be recorded.

16. Statistical Analysis

Data will be entered and analyzed through SPSS version 23. Shapiro–Wilk test will be applied to check normality of quantitative data such as age, ASA grade, size of wound and duration of wound healing. Mean and standard deviation will be calculated for quantitative data, while frequency and percentages will be calculated for categorical variables including gender and site of wound. T-test or Mann–Whitney test will be applied to compare duration of healing in both groups. Stratification will be done with respect to age, gender, ASA grade, size of wound and site of wound. Post-stratification t-test or Mann–Whitney test will be applied. P value < 0.05 will be taken as significant.

17. Ethical Considerations

The study will be conducted after approval of the synopsis from CPSP and permission from the institutional ethical review committee of the hospital. Written informed consent will be obtained from each participant. Participant information will be kept confidential.