STATISTICAL ANALYSIS PLAN

ClinicalTrials.gov Study Document

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

NCT Number: To be assigned by ClinicalTrials.gov
Document Date: September 4, 2026
Document Type: Statistical Analysis Plan
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1. Study 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.

2. Study Design and Groups

This is a randomized controlled trial. A total of 60 patients will be included, with 30 patients in the VAC group and 30 patients in the conventional dressing group. Participants will be randomly divided into the two groups by lottery method.

3. Analysis Population

The planned analysis population will consist of enrolled eligible participants randomized to either study group.

4. Variables

Quantitative variables include age, size of wound and duration of wound healing. Categorical variables include gender, ASA grade and site of wound. Wound surface area and improvement in wound granulation will also be recorded as described in the study protocol.

5. Primary Outcome

The primary outcome is mean duration of wound healing, measured in days.

6. Assessment of Normality

The Shapiro–Wilk test will be applied to check the normality of quantitative data including age, ASA grade, size of wound and duration of wound healing.

7. Descriptive Statistics

Mean and standard deviation will be calculated for quantitative data. Frequency and percentages will be calculated for categorical variables including gender and site of wound.

8. Comparison Between Groups

The duration of wound healing will be compared between the VAC and conventional dressing groups using an independent-samples t-test when appropriate. The Mann–Whitney test will be used when the assumptions for the t-test are not met.

9. Stratified Analysis

Stratification will be performed 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 as appropriate.

10. Statistical Significance

A p-value < 0.05 will be considered statistically significant.

11. Statistical Software

Data will be entered and analyzed using SPSS version 23.

12. Missing Data

The approved synopsis does not specify a separate missing-data imputation method. Missing observations will be reported transparently and analyses will be based on available data as appropriate.