

Cover Page

Statistical Analysis Plan (SAP)

Official Study Title:

Comparison of Wound Infection in Patients Undergoing Primary Closure and Open Technique in The Treatment of Pilonidal Sinus

Brief

Title:

Comparison of Primary closure vs Open wound Technique in Pilonidal Sinus Surgery

ClinicalTrials.gov Identifier

NCT Number: *Not yet assigned*

Unique Protocol ID

RMI_QAD_RCT_PILONOIDAL_sINUS

Study Type

Randomized Controlled Trial (RCT)

Study Sponsor / Conducting Institution

Hayatabad Medical Complex (HMC)

Peshawar, Pakistan

Study Document

Statistical Analysis Plan (SAP)

Responsible party: Dr. Gohar ali

Principal Investigator:

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Ethics Approval:

Approved by Ethical Committee, Hayatabad Medical Complex, Peshawar

Approval Number: RMI_QAD_RCT_PILONOIDAL_sINUS

Document date: May 05, 2025.

Official Study Title:

Comparison of Wound Infection in Patients Undergoing Primary Closure and Open Technique in The Treatment of Pilonidal Sinus

1. Introduction

This SAP outlines the statistical methods that will be used to analyze data from the randomized controlled trial comparing primary closure versus open wound technique in patients undergoing excision of pilonidal sinus. The plan covers analysis of primary and secondary outcomes, handling of missing data, and interpretation of results.

2. Objectives and Outcomes

Primary Objective:

- Compare the incidence of wound infection between primary closure and open technique groups within 30 days postoperatively.

Secondary Objectives:

- Compare wound healing time.
- Compare surgery time.
- Assess the effect of comorbidities (diabetes, hypertension, BMI, age, gender) on wound infection rates.

Primary Outcome:

- Wound infection (Yes/No) within 30 days postoperatively, defined as swelling, redness, and pus/serous discharge at the wound site (Southampton Score).

Secondary Outcomes:

- Hospital stays duration (days).
- Wound healing time (days until complete epithelialization).
- Surgery time (minutes).
- Stratified wound infection rates by comorbidities.

3. Sample Size Calculation

Assumptions:

- Expected wound infection rate: Primary closure 7.69%, Open technique 35.71% (based on prior literature).
- α (two-sided) = 0.05
- Power = 80%

Formula for comparing two proportions:

$$n = \left(\frac{Z_{1-\alpha/2} \cdot \sqrt{2P(1-P)} + Z_{1-\beta} \cdot \sqrt{P_1(1-P_1) + P_2(1-P_2)}}{P_1 - P_2} \right)^2$$

Where:

- $P_1 = 0.0769$ (Primary closure infection rate)
- $P_2 = 0.3571$ (Open technique infection rate)
- $P = (P_1 + P_2)/2$

Calculated Sample Size: 68 participants total (34 per group). To reduce confounding, 76 participants (38 per group) were enrolled.

Analysis Population

All randomized participants will be included in the **intention-to-treat** analysis. Per-protocol analysis will also be conducted for sensitivity.

Descriptive Statistics

- Continuous variables (age, BMI, hospital stay, healing time, surgery time): Mean $\pm$ SD.
- Categorical variables (gender, wound infection, comorbidities): Frequencies and percentages.

Primary Outcome Analysis

- **Test:** Chi-square test to compare wound infection rates between groups.
- **Significance Level:** $p < 0.05$.
- **Effect Size:** Risk difference and risk ratio with 95% confidence intervals.

Secondary Outcome Analysis

- **Healing Time:** Independent t-test (or Mann-Whitney U if non-normal).
- **Surgery Time:** Independent t-test.
- **Comorbidity Effects:** Stratified chi-square tests.

Handling of Missing Data

- Missing outcome data will be handled using multiple imputation if $>5\%$ missing.
- Sensitivity analysis will compare imputed vs complete-case results.

Interim Analysis

No interim analysis planned.

Software

SPSS version 23 will be used for all analyses.