

**Statistical Analysis Plan**

**Official Study Title**

Comparison of Linear Versus Purse-String Skin Closure at Loop Ileostomy Reversal: A  
Randomized Controlled Trial

**Brief Title**

**Comparison of Linear Versus Purse-String Skin Closure at Loop  
Ileostomy Reversal**

**ClinicalTrials.gov Identifier**

NCT Number: Not yet Assigned

**Unique Protocol ID** HMC-QAD-RCT-3

**Study Type** Randomized Controlled Trial (RCT)

**Study Sponsor / Conducting Institution** Hayatabad Medical Complex (HMC) Peshawar,  
Pakistan

**Responsible Party:** Principal Investigator

**Principal Investigator:** Dr. Gohar Ali Principal Investigator Department of Surgery Hayatabad  
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**Study Document** Statistical Analysis Protocol

**Ethics Approval:** Approved by Ethical Committee, Hayatabad Medical Complex, Peshawar  
Approval Number: HMC-QAD-F No. IREB-1680

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## **1. Introduction**

This Statistical Analysis Plan (SAP) describes the statistical methods for analysis of data obtained from a randomized controlled trial comparing linear skin closure versus purse-string skin closure in patients undergoing loop ileostomy reversal. The SAP includes analysis of primary and secondary outcomes, handling of missing data, subgroup analyses, and statistical significance criteria.

## **2. Objectives and Outcomes**

### **Primary Objective**

- To compare the incidence of Surgical Site Infection (SSI) within 30 days after surgery between linear closure and purse-string closure groups.

### **Secondary Objectives**

- To compare length of hospital stay between both groups
- To compare duration of surgery between both groups
- To evaluate postoperative recovery outcomes

### **Primary Outcome**

- Surgical Site Infection (SSI): Yes/No within 30 days after surgery

### **Secondary Outcomes**

- Length of hospital stay (days from surgery to discharge)
- Duration of surgery (minutes from incision to wound closure)

## **3. Sample Size Calculation**

The sample size was calculated based on expected differences in surgical site infection rates between the two techniques with assumptions of:

- Expected SSI rate: Linear closure ~15–40%, Purse-string ~5–10% (based on literature)
- Alpha (two-sided): 0.05
- Power: 80%

Formula for two proportions comparison was used:

$$n = (Z_{1-\alpha/2} \sqrt{2P(1-P)} + Z_{1-\beta} \sqrt{[P_1(1-P_1) + P_2(1-P_2)]})^2 / (P_1 - P_2)^2$$

### **Final Sample Size:**

- 252 participants total

- 126 per group

No additional inflation was required due to complete enrollment.

## **4. Statistical Methods**

### **4.1 General Approach**

Data will be analyzed using **SPSS version 23**.

Descriptive statistics:

- Continuous variables: Mean  $\pm$  standard deviation (SD)
- Categorical variables: Frequency and percentages

Normality will be assessed using Shapiro-Wilk test.

### **4.2 Analysis of Primary Outcome**

**Outcome:** Surgical Site Infection (SSI) (binary)

- Test used: Chi-square test
- Fisher's exact test if expected cell counts  $<5$
- Effect size: Relative Risk (RR) with 95% confidence interval
- Significance level:  $p < 0.05$

### **4.3 Analysis of Secondary Outcomes**

**Length of Hospital Stay (continuous)**

- Independent sample t-test
- If non-normal distribution: Mann–Whitney U test

**Duration of Surgery (continuous)**

- Independent sample t-test
- Report mean difference with 95% CI

### **4.4 Handling Missing Data**

- Missing data will be minimized through complete follow-up
- If missing data  $<5\%$   $\rightarrow$  complete-case analysis
- If  $>5\%$   $\rightarrow$  sensitivity analysis may be performed

### **4.5 Subgroup Analysis**

Subgroup analyses will be performed for:

- Age ( $\leq 40$  vs  $> 40$  years)
- Gender (male vs female)
- BMI categories (normal vs overweight/obese)
- Presence of comorbidities (diabetes/hypertension vs none)

Interaction testing may be performed where appropriate.

#### **4.6 Statistical Significance**

- Two-sided p-value  $< 0.05$  will be considered statistically significant
- All confidence intervals will be reported at 95% level

#### **5. Data Presentation**

- Tables:
  - Baseline demographic characteristics
  - Primary and secondary outcomes
  - Subgroup analyses
- Figures:
  - Bar charts for SSI comparison
  - Box plots for hospital stay duration
  - Bar/line graphs for operative time distribution

#### **6. Statistical Software**

- SPSS version 23
- Microsoft Excel for data organization and visualization

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