**Statistical Analysis Plan (SAP)**

# Official Study Title:
# Comparison of Vicryl Versus Prolene for Midline Rectus Sheath Closure After Elective Laparotomy

## Brief Title:
Comparison of Vicryl Versus Prolene for Midline Rectus Sheath Closure

## ClinicalTrials.gov Identifier
NCT Number: *Not yet assigned*

## Unique Protocol ID
HMC-RECTUS-2019

## 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

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

Document date: May 05, 2024.

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## 1. Introduction

This SAP outlines the statistical methods that will be used to analyze data from the study comparing polyglactin 910 (Vicryl®) and polypropylene (Prolene®) sutures for midline rectus sheath closure in elective laparotomy patients. 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 Surgical site Infections (SSI) between Vicryl and Prolene groups within 30 days postoperatively.

Secondary Objectives:

- Compare rates of Wound dehiscence.
- Compare postoperative pain scores (VAS scale).
- Assess incidence of incisional hernia within 30 days.

Primary Outcome:

- Wound Infections (Yes/No) within 30 days postoperatively.

Secondary Outcomes:

- Wound dehiscence (Yes/No) within 30 days.
- Postoperative pain score (VAS 0–10) at 24h, 48h, 7 days, and 30 days.
- Incisional hernia (Yes/No) within 30 days.

## 3. Sample Size Calculation

Assumptions:

Expected wound SSI and wound dehiscence rate: Vicryl 15%, Prolene 5% (based on prior literature).

α (two-sided) = 0.05

Power = 80%

Formula for comparing two proportions:

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

Calculated Sample Size:

164 participants total (82 per group)

Adjusted for 20% dropout: 200 participants (100 per group)

## 4. Statistical Methods

### 4.1 General Approach

Data will be analyzed using SPSS v26.

Descriptive statistics will summarize baseline characteristics:

Continuous variables: mean ± SD (if normally distributed) or median [IQR] (if skewed).

Categorical variables: frequency (%)

### 4.2 Analysis of Primary Outcome

Outcome: Wound dehiscence (binary)

Method: Chi-square test or Fisher's exact test (if expected cell counts <5)

Effect measure: Risk difference and relative risk with 95% CI

### 4.3 Analysis of Secondary Outcomes

SSI (binary): Chi-square test; risk difference and 95% CI

Postoperative pain (continuous, VAS):

Repeated measures ANOVA or mixed-effects model for 24h, 48h, 7-day, 30-day scores

Post-hoc pairwise comparisons with Bonferroni correction

Incisional hernia (binary): Chi-square test; 95% CI

### 4.4 Handling Missing Data

Missing primary outcome data will be minimized via complete follow-up.

If <5% missing, complete-case analysis will be used.

If >5% missing, multiple imputation may be considered.

### 4.5 Subgroup Analysis

Age (<50 vs ≥50), sex (male vs female), BMI (<25 vs ≥25)

Interaction between suture type and subgroup assessed using logistic regression

### 4.6 Significance Level

Two-sided p-value <0.05 considered statistically significant.

## 5. Data Presentation

Tables: Baseline characteristics, primary and secondary outcomes, subgroup analyses

Figures: Bar charts for SSI and wound dehiscence rates; line graph for VAS pain scores over time

## 6. Software

- SPSS version 26 for statistical analysis
- Microsoft Excel for graphical presentation.