

Statistical Analysis Plan

Video-Assisted Ablation of Pilonidal Sinus (VAAPS) Combined with Loose
Glove-Edge Seton Drainage for Postoperative Self-Care: A Prospective Single-Arm
Cohort Study (PKUPH-PS01)

Sponsor: Peking University People's Hospital

Principal Investigator: Bozhi Hu, MD, MD

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This document contains no identifiable participant information.

1. Overview

This Statistical Analysis Plan (SAP) describes the statistical methods for the PKUPH-PS01 study. All analyses will be performed using SPSS 26.0 and R 4.3.1. Two-sided tests will be used, with $P < 0.05$ considered statistically significant.

2. Analysis Populations

Full Analysis Set (FAS): all enrolled participants who undergo VAAPS with loose seton and have at least one postoperative follow-up assessment. Per-Protocol (PP) set: participants who complete the study without major protocol deviations.

3. Descriptive Statistics

Continuous variables will be presented as mean $\pm$ standard deviation (SD) or median (interquartile range, IQR) depending on distribution normality. Categorical variables will be presented as frequencies and percentages.

4. Primary Outcome Analysis

Time off work, time to wound healing, and VAS pain scores will be summarized with means, SDs, medians, IQRs, and 95% confidence intervals. Repeated-measures ANOVA will be used to analyze the trend of VAS pain scores over time.

5. Recurrence Analysis

Recurrence-free survival will be estimated using the Kaplan-Meier method. One-year and 3-year recurrence rates with 95% CIs will be reported. Participants without recurrence at last follow-up will be censored.

6. Subgroup Analyses

Subgroup analyses will be performed by: complex vs. simple disease, age, BMI, smoking status, and dressing method (self-care vs. local hospital). Continuous variables will be compared using t-tests or Wilcoxon rank-sum tests; categorical variables using chi-square or Fisher's exact tests.

7. Predictive Factor Analysis

Univariate Cox regression will be used to screen factors associated with recurrence. Variables with $P < 0.1$ in univariate analysis will be entered into a multivariate Cox regression model to identify independent prognostic factors.

8. Historical Comparison

Primary outcomes will be descriptively compared with published VAAPS cohorts (Milone 2016 JAMA Surg; Meinerio 2016 Tech Coloproctol) to contextualize the results.

9. Missing Data

Missing data will be handled using multiple imputation where appropriate. Loss to follow-up will be reported as a percentage. Sensitivity analyses will be performed to assess the impact of missing data on recurrence estimates.