

Title: The Efficacy of Adjuvant Oral Care in Prevention of Ventilator-Associated Pneumonia

- **ClinicalTrials.gov Identifier**
 - **NCT06039995**
- **Study Design**
 - Randomized Controlled Trial
- **Sponsor / Responsible Party**
 - University of Health Sciences
- **Study Site**
 - Services Hospital, Lahore, Pakistan
- **Principal Investigator**
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- **Document Type**
 - Statistical Analysis Plan (SAP)
- **SAP Version**
 - Version 1.0
- **Document Date**
 - 15 December 2025

Statistical Analysis Plan (SAP)

- **Analysis Population**

- All randomized participants (n=100) were included in the analysis, with 50 patients in each study arm. No attrition was reported.

- **Descriptive Statistics**

- Continuous variables (age, ICU stay) were summarized using means and standard deviations.
- Categorical variables (sex, VAP incidence, mortality) were summarized using frequencies and percentages.

- **Primary Outcome Analysis**

- The incidence of VAP was compared between intervention and control groups using a chi-square test or Fisher's exact test, as appropriate. The level of statistical significance was set at $p < 0.05$.

- **Secondary Outcome Analyses**

- **Duration of ICU Stay:** Compared between groups using an independent-samples t -test, assuming approximate normality.
- **Mortality Rates:** Compared using chi-square analysis.

- **Assumptions and Verification**

- Normality assumptions for continuous outcomes were assessed using descriptive distribution checks.
- Equality of variances was evaluated prior to parametric testing.
- No adjustments for multiple comparisons were applied, as secondary outcomes were exploratory.

- **Handling of Missing Data**

- No missing outcome data were reported; therefore, no imputation methods were required.

- **Safety Analysis**

- Adverse events were summarized descriptively. Serious and non-serious adverse events were compared between groups. No intervention-related adverse events were reported.