

# **Official Study 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**
  - Study Protocol
- **Protocol Version**
  - Version 1.0
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# Study Protocol

- **Title**
  - The Efficacy of Adjuvant Oral Care in the Prevention of Ventilator-Associated Pneumonia: A Randomized Controlled Trial
- **Background and Rationale**
  - Ventilator-associated pneumonia (VAP) is a common and serious complication among mechanically ventilated patients in intensive care units (ICUs). Oral colonization by pathogenic microorganisms is a recognized contributor to VAP development. Enhanced oral care strategies combining mechanical and chemical interventions may reduce microbial load and subsequent pulmonary infection. This study evaluates whether adjuvant oral care provides benefit beyond traditional oral hygiene practices.
- **Objectives**
  - **Primary Objective:**
    - To compare the incidence of ventilator-associated pneumonia between patients receiving adjuvant oral care and those receiving traditional oral care.
  - **Secondary Objectives:**
    - To compare the duration of ICU stay between the two groups.
    - To compare mortality rates during ICU admission between the two groups.
- **Study Design**
  - This was a single-centre, parallel-group, randomized controlled trial conducted over a three-month period at Services Hospital, Lahore. A total of 100 mechanically ventilated adult patients were enrolled and randomly allocated in a 1:1 ratio to either the intervention or control group.
- **Study Population**
  - Adult patients (18–65 years) admitted to the ICU and receiving mechanical ventilation were eligible. All participants were enrolled from Pakistan. Baseline characteristics, including age and sex distribution, were comparable between groups.
- **Interventions**
  - **Intervention Group (Adjuvant Oral Care):**

Patients received comprehensive oral care consisting of:

    - 0.2% chlorhexidine mouthwash
    - Mechanical toothbrushing using chlorhexidine
    - Application of moisturizing gel to interior and exterior oral surfaces
  - **Control Group (Traditional Oral Care):**
    - Patients received routine oral care using cotton swabs dipped in 0.2% chlorhexidine mouthwash only.
- **Outcome Measures**
  - **Primary Outcome:** Incidence of ventilator-associated pneumonia during ICU stay.
  - **Secondary Outcomes:** Duration of ICU stay (days) and mortality during ICU admission.
- **Ethical Considerations:** The study was conducted following approval from the relevant human subject's protection review board. No protocol amendments affecting all study sites were reported. There were no restrictions on publication rights for investigators.