01/11/2026

INVESTIGATION OF THE EFFECT OF TWO DIFFERENT ORAL CARE METHODS ON ORAL FLORA AND VENTILATOR ASSOCİATED PNEUMONIA IN MECHANİCALLY VENTİLATED PATIENTS:

A RANDOMIZED CONTROLLED STUDY

NCT ID: NCT07283380

1. Title

The Effect of Two Different Oral Care Methods (Paediatric Toothbrush and Sponge Swab) on Oral Flora and Ventilator-Associated Pneumonia in Mechanically Ventilated ICU Patients: A Randomized Controlled Trial

2. Acronym

ORAVAP-RCT

3. Background

In critically ill patients receiving mechanical ventilation, changes in oral microflora may occur within 48 hours of intubation, with potentially pathogenic Gram-negative bacteria increasingly colonising the oral cavity (Miranda et al., 2016; Karateke and Terzi, 2021). Ventilator-associated pneumonia (VAP) is associated with increased mortality, prolonged hospital stays, greater antibiotic use and increased healthcare costs (Özveren, 2010).

Although both sponge swabs and toothbrushes are used for oral care in intensive care units (ICUs), their comparative effectiveness in reducing oral microbial colonisation and preventing VAP remains uncertain. Evaluating these methods may contribute to the development of evidence-based oral care practices for mechanically ventilated patients.

4. Objectives and Hypotheses

Objective: To compare the effects of two oral care methods (paediatric toothbrush versus sponge swab) on oral microbial colonisation and the incidence of VAP in mechanically ventilated ICU patients.

Hypothesis: Oral care performed using a paediatric toothbrush is more effective than oral care performed using a sponge swab in reducing oral bacterial colonisation and the incidence of VAP.

5. Study Design

Type: Randomized controlled trial

Model: Parallel- group design (two arms)

Masking: Single-blind (independent outcome assessors)

Allocation: Randomized (1:1)

6. Study Setting and Participants

The study is being conducted in the Anaesthesia and General Intensive Care Unit of Zonguldak Atatürk State Hospital, Türkiye. The study commenced in October 2025, with completion planned for March 2027.

Inclusion Criteria

- Age ≥18 years,
- Receiving invasive mechanical ventilation within the first 24 hours following intubation.
- Written informed consent obtained from their legally authorized reprensative.

- No history of oral/maxillofacial surgery or head and neck trauma,
- No contraindications to oral care.

Exclusion Criteria

- Age <18 years,
- Diagnosed pneumonia prior to intubation,
- Absence of informed consent.
- Contraindications to oral care.

7. Interventions

Arm 1 (Experimental): Oral care using a paediatric toothbrush.

Arm 2 (Active Comparator): Oral care using a sponge swab.

Both groups will receive oral care for five consecutive days. A 0.12% chlorhexidine solution will be used twice daily in both groups. Additional oral care will be provided using normal saline, with the frequency determined by the Oral Care Assessment Scale for Intensive Care Patients (OCAS-ICP).

8. Outcome Measures

Primary Outcome 1: Changes in Oral Microbial Colonisation

Oropharyngeal swab samples will be collected on Days 1 and 6 to assess the presence or absence of growth of bacterial pathogens associated with ventilator-associated pneumonia and Candida species. Changes in oral microbial colonisation will be evaluated by comparing the culture results for each microorganism between Days 1 and 6.

Primary Outcome 2: Incidence of Ventilator-Associated Pneumonia (VAP)

The development of VAP will be determined through clinical assessment by the treating physician, supported by the Clinical Pulmonary Infection Score (CPIS).

The CPIS includes six parameters: body temperature, leukocyte count, tracheal secretions, oxygenation (PaO_2/FiO_2), chest radiographic findings and microbiological culture results.

The total score ranges from 0 to 12, with higher scores indicating a greater likelihood of pulmonary infection. VAP incidence will be recorded as present or absent, with assessments performed on Days 1 and 6.

Secondary Outcome: Oral Care Frequency

Oral care frequency will be assessed using the Oral Care Assessment Scale for Intensive Care Patients (OCAS-ICP), developed by the researchers.

The scale comprises 10 parameters and 17 factors, with a total score ranging from 0 to 26. Higher scores indicate poorer oral health status and greater oral care needs.

Oral care frequency will be determined according to the total score:

- 0–8 points: twice daily.
- 9–17 points: four times daily.
- 18–26 points: six times daily.

Patients will be assessed daily from Day 1 to Day 5.

9. Sample Size

The sample size was revised based on the pathogen colonisation rates reported by Needleman et al. (2011), with assumed rates of 46% in the control group and 5% in the intervention group.

Using a two-sided Fisher's exact test with a significance level of 0.05 and approximately 80% statistical power, the minimum required sample size was estimated at 38 patients (19 per group).

To account for potential participant losses, the sample size was increased by 20%, resulting in a planned enrolment of 46 patients (23 per group).

10. Randomization and Masking

Participants will be randomly allocated to one of two groups in a 1:1 ratio using computer-generated block randomisation.

Due to the nature of the interventions, nurses providing oral care will not be blinded to group allocation. However, microbiology laboratory personnel assessing culture results and independent outcome assessors evaluating VAP development will remain blinded to group allocation.

11. Data Collection and Measurements

Introductory Information Form: Baseline demographic and clinical characteristics of participants.

Microbiology Patient Follow-up Form: Oropharyngeal swab culture results obtained on Days 1 and 6, including the presence or absence of microbial growth.

CPIS Patient Follow-up Form: Clinical Pulmonary Infection Score assessments and VAP status recorded on Days 1 and 6.

Oral Care Assessment Scale for Intensive Care Patients (OCAS-ICP): Daily assessment of oral care needs and determination of oral care frequency from Day 1 to Day 5.

12. Statistical Analysis Plan (SAP)

Descriptive statistics will be presented as means, standard deviations, medians, frequencies and percentages, as appropriate.

Between-group comparisons will be performed using the chi-square test, Fisher's exact test, independent-samples t-test or Mann–Whitney U test, as appropriate.

Within-group changes between Days 1 and 6 will be assessed using appropriate paired statistical tests, depending on the type and distribution of the data.

Oral care assessment scores will be evaluated over the five-day intervention period.

All statistical tests will be two-sided, with a significance level of $p < 0.05$. Any deviations from the planned analyses will be documented and justified.

13. Ethical Considerations

The study was approved by the Koşuyolu High Specialisation Training and Research Hospital Clinical Research Ethics Committee.

Written informed consent will be obtained from patients or their legally authorised representatives.

14. Timeline

Data collection: October 2025 – March 2027

Statistical analysis: Following completion of data collection.

Publication: Following completion of the study and statistical analysis.

15. References

Miranda AL, et al. (2016). Oral care practices for patients in Intensive Care Units: A pilot survey. Indian J Crit Care Med, 20(5), 267-73. doi: 10.4103/0972-5229.182203. PMID: 27275074; PMCID: PMC4876647.

Karateke F, Terzi A. (2021). Investigation of ventilator-related pneumonıa (VAP) intensive care in Intensive Care Units, investigating the intervention of ventilator-related pneumonia: A systematıc revıew. Journal of Intensive Care Nursing, 25(1), 1-9.

Ozveren H. (2010). Oral Care in Patients Receiving Mechanical Ventilator. Hacettepe University Faculty of Health Sciences Nursing Journal, 17(2), 92-99.

Needleman IG, Hirsch NP, Leemans M, Moles DR, Wilson M, Ready DR, Ismail S, Ciric L, Shaw MJ, Smith M, Garner A, Wilson S. Randomized controlled trial of toothbrushing to reduce ventilator-associated pneumonia pathogens and dental plaque in a critical care unit. J Clin Periodontol. 2011 Mar;38(3):246-52. doi: 10.1111/j.1600-051X.2010.01688.x. Epub 2011 Jan 11. PMID: 21223352.