02/11/2026

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

INFORMED CONSENT FORM

Study Title:

Effect of Two Different Oral Care Methods on Oral Flora and Ventilator-Associated Pneumonia in Mechanically Ventilated ICU Patients

Purpose of the Study:

The purpose of this study is to investigate the effects of different oral care methods (paediatric toothbrush versus sponge swab) on oral flora and the risk of ventilator-associated pneumonia (VAP) in mechanically ventilated ICU patients.

Study Duration:

Each patient will be followed for six days. Oral care will be provided for five consecutive days.

Procedures:

Patients will be randomly assigned to receive oral care using either a paediatric toothbrush or a sponge wab.

Both groups will receive oral care with 0.12% chlorhexidine solution twice daily. Additional oral care will be provided using normal saline, with the frequency determined by the patient's oral care assessment.

Oropharyngeal swab samples will be collected on Days 1 and 6. Routine blood test results and chest radiographs will be reviewed as part of the clinical assessment.

Oral care will be provided by ICU nurses or study investigators. Oral care will be provided by ICU nurses or study investigators.

Number of Participants:

A total of 46 patients (23 patients per group) are planned to be enrolled in the study.

Risks and Discomforts:

Oral swab collection and oral care may cause temporary mild discomfort, irritation or minor bleeding.

Ventilator-associated pneumonia may still develop despite the provision of oral care.

Benefits:

Participants may experience improved oral hygiene. However, a direct clinical benefit cannot be guaranteed.

The findings of this study may contribute to the improvement of oral care practices in intensive

care units.

Voluntary Participation:

Participation in this study is entirely voluntary.

The participant or their legally authorised representative may withdraw consent at any time.

Refusal to participate or withdrawal from the study will not affect the participant's medical care.

Confidentiality:

All participant information will be kept confidential.

Research data will be handled in accordance with applicable data protection requirements and used for scientific research purposes.

Contacts for Questions:

Anesthesiology Specialist ……

PhD Candidate …….

Consent:

I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers.

I voluntarily consent to participation in this study, either on my own behalf or, where legally authorised, on behalf of the patient identified below.

I understand that participation is voluntary and that I will receive a copy of this consent form.

Participant Name ……

Legal Representative Name and Signature (if applicable): ……

Investigator Name and Signature: ……

Witness Name, Signature, Role (if applicable): ……

Date: … / … / …