

24/09/2025

**INVESTIGATION OF THE EFFECT OF TWO DIFFERENT ORAL CARE  
METHODS ON ORAL FLORA AND VENTILATOR ASSOCIATED PNEUMONIA IN  
MECHANICALLY VENTILATED PATIENTS:  
A RANDOMIZED CONTROLLED STUDY**

NCT ID not yet assigned

## **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 (pediatric toothbrush vs. sponge stick) on oral flora and the risk of ventilator-associated pneumonia (VAP) in mechanically ventilated ICU patients.

### **Study Duration:**

Each patient will be followed for 6 days.

### **Procedures:**

Patients will receive daily oral care using either a pediatric toothbrush or sponge stick with 0.12% chlorhexidine solution.

Oral swab samples will be collected on Day 1 and Day 6 (approximately 20 minutes).

Routine blood tests and chest X-rays will be monitored.

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

### **Number of Participants:**

A total of 72 patients (36 per group)

### **Risks and Discomforts:**

Oral swab collection is brief and poses no harm.

Mild discomfort may occur during oral care.

Pneumonia may still develop in some patients despite oral care.

### **Benefits:**

Patients may have improved oral hygiene and reduced risk of VAP.

The study may help improve oral care protocols in ICUs.

### **Voluntary Participation:**

Participation is completely voluntary.

You can withdraw from the study at any time.

Choosing not to participate will not affect your medical care.

**Confidentiality:**

Patient information will be kept confidential.

Data will be used only for scientific research purposes.

**Contacts for Questions:**

Anesthesiology Specialist Physician .....

PhD Candidate .....

**Consent:**

I have read and understood the information above. I voluntarily consent for my ICU patient to participate in this study without any pressure. I will receive a copy of this form.

Participant Name and Signature: .....

Guardian Name and Signature (if applicable): .....

Investigator Name and Signature: .....

Witness Name, Signature, Role: .....

Date: ... / ... / ...