

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### The Comparison of three methods of endotracheal tube cuff pressure regulation in patients with mechanical ventilation on incidence of ventilator-associated pneumonia

#### Protocol summary

##### Summary

Purpose of this study is the comparison of three methods of regulation in endotracheal tube cuff pressure on incidence of ventilator-associated pneumonia. Design of study: This is a randomized, single blind trial with three groups. Inclusion criteria: patients aged 18-65 years, orotracheal tube, and expectation for mechanical ventilation more than 72 hours. Exclusion criteria: tracheostomy tube, death or disconnection from mechanical ventilation during the study, suppression of immune system, approved pneumonia before the study, massive aspiration, patients with malignancy, reintubation, and changing of cuff pressure out of the design of study. In this study 60 patients will be divided to three groups and will be homogenized about APACHE number and level of consciousness with randomized block design. In group 1 endotracheal tube cuff pressure will be regulated with estimating method by experienced person. In group 2 this regulation will be performed with minimal leak during inspiration and in group 3 endotracheal tube cuff pressure will be regulated with manometer in 25 cmH<sub>2</sub>O. These interventions are performed twice a day for 4 days. In the first day and fourth day scores of clinical pneumonia are compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111256481N2**

Registration date: **2011-12-12, 1390/09/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-12-12, 1390/09/21

#### Registrant information

##### Name

Mohsen Soleimani

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

sol257@semums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Semnan University of Medical Sciences

#### Expected recruitment start date

2012-02-10, 1390/11/21

#### Expected recruitment end date

2013-06-10, 1392/03/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Comparison of three methods of endotracheal tube cuff pressure regulation in patients with mechanical ventilation on incidence of ventilator-associated pneumonia

#### Public title

The Comparison of three methods of endotracheal tube cuff pressure regulation on ventilator-associated pneumonia

#### Purpose

Prevention

## **Inclusion/Exclusion criteria**

Inclusion criteria: Age 18-65 years; Orotracheal tube; Expectation for mechanical ventilation for more than 72 hours. Exclusion criteria: Patients with tracheostomy tube; dying or disconnection from mechanical ventilation before completing study; Immune system suppression; approved pneumonia before start of study; massive aspiration; malignancy; reintubation; change in cuff pressure out of study.

### **Age**

From **18 years** old to **65 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

randomized block design for some features in groups

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Semnan University of Medical Sciences

##### **Street address**

Semnan University of Medical Sciences

##### **City**

Semnan

##### **Postal code**

3513138111

#### **Approval date**

2011-11-14, 1390/08/23

#### **Ethics committee reference number**

A-10-18-2

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

patients with mechanical ventilation

#### **ICD-10 code**

J69.0

#### **ICD-10 code description**

Pneumonitis due to food and vomit

## **Primary outcomes**

### **1**

#### **Description**

Ventilator Associated Pneumonia

#### **Timepoint**

Before intervention and 4 days later

#### **Method of measurement**

Clinical pneumonia index

## **Secondary outcomes**

### **1**

#### **Description**

Administration time in ICU

#### **Timepoint**

From administration to discharge

#### **Method of measurement**

Counting

## **Intervention groups**

### **1**

#### **Description**

Group1: regulation of edotracheal tube cuff pressure with estimation method.

#### **Category**

Prevention

### **2**

#### **Description**

Group2: regulation of edotracheal tube cuff pressure with minimal leak method.

#### **Category**

Prevention

### **3**

#### **Description**

Group3: regulation of edotracheal tube cuff pressure with manometer method.

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Fatemieh Hospital

##### **Full name of responsible person**

Dr. Mohsen Soleimani

**Street address**

Fatemieh Hospital, 17 shahrivar avenue

**City**

Semnan

**2****Recruitment center****Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Dr. Mohsen Soleimani

**Street address**

Rasool akram Hospital, Satarkhan avenue

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Raheb Ghorbani

**Street address**

Semnan University of Medical Sciences, Basij avenue

**City**

Semnan

**Grant name**

-

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Soleimani

**Position**

PhD of nursing

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**Web page address****Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty