Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 cmH2o. 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

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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
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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
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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

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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