Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of usual endotracheal tube replacement with endotracheal tube with capability of subglottic suction on reduction of ventilator associated pneumonia in patients admitted in adults intensive care units medical sciences

Protocol summary

Summary

Objective: To evaluate the effect of usual endotracheal tube replacement with endotracheal tube with capability of subglottic suction on reduction of ventilator associated pneumonia in patients admitted in adults intensive care units. Study Design: a randomized, double-blind study. Intervention: 128 patients under mechanical ventilation in the ICU are divided into two groups. Patients in the control group are under mechanical ventilation with conventional endotracheal tube (7 or 7.5 mm internal diameter for women and 8 or 8.5 mm for men) In the case group patients' previous tracheal tube to be replaced with tracheal tube with capability of subglottic suction (inner diameter of 7 or 5.7 mm for women or 8 or 8.5 mm for men). If patients require tracheostomy tube, at the controls we use conventional tracheostomy tube while tracheostomy with capability of subglottic suction in cases. Inclusion criteria: age over 18; patients with endotracheal tube in the ICU, mechanical ventilation for more than 48 hours, pneumonia before intubation and mechanical ventilation, cardiac disease. Exclusion criteria: immune deficiency, using immune system inhibitor drugs (cytotoxic chemotherapy or corticosteroids more than 160 mg hydrocortisone, prednisone 40 mg, 6 mg of dexamethasone or its equivalent; extubation less than 48 hours after intubation; death less than 48 hours after intubation, difficult intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509266651N1**
Registration date: **2016-04-25, 1395/02/06**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-04-25, 1395/02/06

Registrant information

Name
Mohsen Savaie
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Science

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of usual endotracheal tube replacement with endotracheal tube with capability of subglottic suction on reduction of ventilator associated pneumonia in patients admitted in adults intensive care units medical sciences

Public title
The effect of usual endotracheal tube replacement with endotracheal tube with capability of subglottic suction on reduction of ventilator associated pneumonia in patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age over 18; patients with endotracheal tube in the ICU, mechanical ventilation for more than 48 hours, pneumonia before intubation and mechanical ventilation, cardiac disease. Exclusion criteria: immune deficiency, using immune system inhibitor drugs (cytotoxic chemotherapy or corticosteroids more than 160 mg hydrocortisone, prednisone 40 mg, 6 mg of dexamethasone or its equivalent; extubation less than 48 hours after intubation; death less than 48 hours after intubation, difficult intubation.
Age
From **18 years** old to **139 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor of research, Shiaz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Postal code
Approval date
2015-12-01, 1394/09/10
Ethics committee reference number
IR.SUMS.Med.RED.1394.135

Health conditions studied

1

Description of health condition studied
Pneumonia
ICD-10 code
J15
ICD-10 code description
Bacterial pneumonia, not elsewhere classified

Primary outcomes

1

Description
ventilator associated pneumonia
Timepoint
DAILY
Method of measurement
2015 GUIDLINE ,Centers for Disease Control(CDC)

Secondary outcomes

empty

Intervention groups

1

Description
Patients in the control group are under mechanical ventilation with conventional endotracheal tube (7 or 7.5 mm internal diameter for women and 8 or 8.5 mm for men)
Category
Prevention

2

Description
In the case group patients' previous tracheal tube to be replaced with tracheal tube with capability of subglottic suction (inner diameter of 7 or 5.7 mm for women or 8 or 8.5 mm for men).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Dr Mohsen Savaie
Street address
Namazi squer, Namazi Hospital
City

Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiaz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences ,Zand streetl
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shiaz 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
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Person responsible for scientific inquiries

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Web page address

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