

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36474270

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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

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

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Savaie

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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