

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of an upper respiratory care program on incidence of ventilator-associated pneumonia in mechanically ventilated patient in Al-Zahra hospital intensive care units, Isfahan University of Medical Sciences.

Protocol summary

Summary

Objective: effect of an upper respiratory care program on incidence of ventilator-associated pneumonia in mechanically ventilated patient in Al-Zahra hospital intensive care units, Isfahan University of Medical Sciences, 2014. Study Design: randomized clinical trial. Study population: patients admitted to intensive care units of Esfahan Al-Zahra hospital. Inclusion criteria: willingness to participate in the study: Patients above 18, mechanical ventilation for more than 24 hr, free of pneumonia or respiratory infections by the time of arrival to the hospital, free of pneumonia before intubation, free of pneumonia in the first 48 hr of intubation, free of limitations due to head elevation. In intervention group the patients were taken under an upper respiratory care program including oral and subglottic secretion suction before every position change, head elevation during the treatment and measuring and controlling the trachea cuff pressure twice a day, in the control group the upper respiratory care program is carried out as the routine protocol. Interference: during the first 5 days of intubation the upper respiratory care program was applied to the interference group. Evaluation of ventilator-related pneumonia variables carried out in control and intervention group during the 5 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122215898N1**
Registration date: **2014-05-10, 1393/02/20**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-10, 1393/02/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an upper respiratory care program on incidence of ventilator-associated pneumonia in mechanically ventilated patient in Al-Zahra hospital intensive care units, Isfahan University of Medical Sciences.

Public title

The effect of an upper respiratory care program on incidence of ventilator-associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Patients above 18,mechanical ventilation more than 24 hr,free of pneumonia or hospital infections before and in the first 48 hr of intubation, free of invasive antibiotics, free of limitations due to head position of medical bed, Exclusion Criteria: Death before the end of the study, extubation before the end of the study,Transfer to other wards or hospitals before the end of the study, undergoing surgery during the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Isfahan university of medical science.

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib,Isfahan Isfahan Isfahan Iran, Islamic Republic Of 461-81746

City

Isfahan

Postal code

Approval date

2014-05-05, 1393/02/15

Ethics committee reference number

391295

Health conditions studied

1

Description of health condition studied

Ventilator Associated Pneumonia

ICD-10 code

J95.9

ICD-10 code description

Postprocedural respiratory disorder, unspecified

Primary outcomes

1

Description

Incidence of Ventilator Associated Pneumonia

Timepoint

Before intervention, day 3, day 4, day 5,

Method of measurement

Clinical Pulmonary Infection Score, CPIS.

Secondary outcomes

empty

Intervention groups

1

Description

In the Intervention group, the upper respiratory care program was carried out, which included oral and subglottic secretion suction with 100-140 mmHg before each change position, head elevation every 12 hours (8am-8pm) using Oblique resulting the patient being fixed in 45°,measuring the trachea cuff pressure twice a day every 12 hours (8 am-8pm) resulting in the fixed interval of 20-30 mmH2O.

Category

Prevention

2

Description

In control group patients were taken under routine upper respiratory care, including oral and subglottic secretion suction every two hours for patients under mechanical ventilation independent of the position change routines. Measuring and controlling the trachea cuff pressure were not carried under any special protocols depending on the environmental characteristics. head elevation was taken under consideration but not documented.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of
Medical Sciences
Full name of responsible person
Dr Peiman Adibi
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Isfahan University of Medical Sciences, Azadi Square,
Hezar-Jerib street, Isfahan.
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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, Isfahan 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 updating data

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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