

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of endotracheal tube cuff pressure (minimum/maximum) in the prevention of ventilator-induced pneumonia in patients admitted to ICU

Protocol summary

Study aim

Determining and comparing the incidence of late-onset pneumonia in the two studied groups

Design

Patients will be divided into groups by block randomization method (block size 4). Randomization is performed by an epidemiologist or using the online program at sealedvelope.com. Due to the double-blind nature of the study, the data collector and the data analyst do not know about our grouping, but the anesthesiologist who is on the patient's bed during surgery knows about the grouping

Settings and conduct

The intervention is performed in the ICU of Valiasr Hospital. In this study, the patients, as well as the project data analyst and the intern who is responsible for completing the questionnaires, will be unaware of the division of patients into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients requiring mechanical ventilation Age 18 to 65 years! Absence of lung disease and lung mass! No use of chemotherapy drugs! Absence of enteral nutrition! Failure to receive antibiotics prior to onset of VAP Exclusion criteria Patients who require mechanical ventilation for less than 48 hours (because they are at low risk of VAP)! death! Lack of consent to participate in the study by the guardian Reintubation

Intervention groups

Intervention group: In one group, the cuff pressure is considered to be at least normal and its amount will be 20 to 22 cm of water. In order to check the cuff pressure, it will be measured by a manometer every 4 hours. Intervention group: cuff pressure will be considered as maximum normal and its amount will be 30 to 32 cm of water. In order to check the cuff pressure, it will be measured by a manometer every 4 hours.

Main outcome variables

Duration of mechanical ventilation and mortality and incidence of pneumonia with early onset and late onset

in patients will be recorded. The severity of the disease will be recorded daily for three days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230730058978N1**

Registration date: **2023-10-08, 1402/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-08, 1402/07/16**

Update count: **0**

Registration date

2023-10-08, 1402/07/16

Registrant information

Name

Milad Ghaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3722 9462

Email address

miladlytod@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-27, 1402/07/05

Expected recruitment end date

2023-10-17, 1402/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of endotracheal tube cuff pressure (minimum/maximum) in the prevention of ventilator-induced pneumonia in patients admitted to ICU

Public title

The effect of endotracheal tube cuff pressure (minimum/maximum) in the prevention of ventilator-induced pneumonia in patients admitted to ICU

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in need of mechanical ventilation, age 18 to 65 years absence of lung disease and lung mass absence of chemotherapy drugs absence of enteral nutrition absence of antibiotics before the start of VAP

Exclusion criteria:

Patients who require mechanical ventilation for less than 48 hours (because they are at low risk of VAP). Lack of consent to participate in the study by the guardian
Reintubation

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: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into 2 groups by block randomization method (block size 4). Case sequencing is performed by an epidemiologist using an online program at www.sealedvelope.com. Hiding the random chain is done by the method of opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the double-blind nature of the study, the patients and the data collector and the data analyst do not know about the groupings, but the anesthesiologist who is at the patient's bedside during surgery and knows about the grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Arak Medical University

Street address

Sardasht - arak medical university

City

arak

Province

Markazi

Postal code

3848176941

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.ARAKMU.REC.1401.279

Health conditions studied**1****Description of health condition studied**

Ventilator-associated Pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes**1****Description**

ventilator-associated pneumonia

Timepoint

During the intervention and 4 days after the intervention

Method of measurement

Cuff Pressure Measurement

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In a group, cuff pressure is considered as minimum normal and its amount will be 20 to 22 cm of water .

Category

Treatment - Devices

2**Description**

Intervention group: and another group The cuff pressure will be considered as maximum normal and its amount

will be 30 to 32 cm of water.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

valiaasr hospital

Full name of responsible person

Milad Ghaffari

Street address

Valiaasr squar., Valiaasr hospital

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Web page address

<https://arakmu.ac.ir/valiasrhos/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

davood hekmatpou

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

valiaasr hospital

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

behnam mahmudie

Position

Associate Professor of Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

behnam mahmudie

Position

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Latest degree

Subspecialist

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Person responsible for updating data

Contact

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Position

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Latest degree

Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available