Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 sealedevelope.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.sealedevelope.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

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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
Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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