

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of bactiguard infection protection endotracheal tube on ventilator-associated pneumonia occurrence in patients admitted to intensive care unit

Protocol summary

Study aim

Effect of bactiguard infection protection endotracheal tube on ventilator-associated pneumonia occurrence in patients admitted to intensive care unit

Design

This study is clinical trial and double blind.108 patients with ventilator-associated pneumonia in ICU in Valiasr Hospital in Arak will inter this study.We will divide patients in 2 groups by simple randomization.Groups are parallel.

Settings and conduct

This study is clinical trial and double blind.108 patients with ventilator-associated pneumonia in ICU part in Valiasr Hospital in Arak will enter this study.Outcome assessor and analyzer don't aware from grouping.We record leukocytosis, volume of discharge, decrease in oxygen saturation, fever and illness severity.

Participants/Inclusion and exclusion criteria

Inclusion criteria:18 to 60 years; a level of consciousness less than 10 Exclusion criteria: Dissatisfaction

Intervention groups

Patients who enter the first group will receive a bactiguard infection protection endotracheal tube.Patients entering the second group will receive a conventional ordinary endotracheal tube.

Main outcome variables

Leukocytosis, volume of discharge, decrease in oxygen saturation, fever and illness severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N132**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **retrospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of bactiguard infection protection endotracheal tube on ventilator-associated pneumonia occurrence in patients admitted to intensive care unit

Public title

Effect of respiratory tube on pneumonia occurrence in patients admitted to intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 60 years A level of consciousness less than 10

Exclusion criteria:

No history of pulmonary disease No pulmonary involvement

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee Of Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.ARAKMU.REC.1397.024

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**

Volume of discharge

Timepoint

Before start intervention and first and second days after intervention

Method of measurement

Milliliter

2**Description**

Leukocytosis

Timepoint

Before start intervention and first and second days after intervention

Method of measurement

Blood test

3**Description**

Decrease in oxygen saturation

Timepoint

Before start intervention and first and second days after intervention

Method of measurement

Pulse Oximeter

4**Description**

Fever

Timepoint

Before start intervention and first and second days after intervention
Method of measurement
Thermometer

5

Description

Illness severity

Timepoint

Before start intervention and first and second days after intervention

Method of measurement

APACHE II score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients who enter the first group will receive a BIP endotracheal tube (Nova tex Co). The endotracheal tube is inserted into the section from the beginning. The endotracheal tube is made of silver. Bacterial colonization and pneumonia symptoms can be effective. Patients are provided with tracheal tube upon arrival.

Category

Treatment - Devices

2

Description

Intervention group: Patients entering the second group will receive a conventional ordinary endotracheal tube (Nova tex). The endotracheal tube is inserted into the section from the beginning.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University Of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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, Arak University Of Medical Sciences

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

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Specialist

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Position

medicine student

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Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Mahmodie

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments