

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of the routine procedure and the routine procedure supplemented by bronchoscopic suctioning in treating ventilator-associated pneumonia in patients admitted to the surgical intensive care unit

Protocol summary

Study aim

Investigating the effect of adding bronchoscopic suction of secretions to the routine treatment of ventilator-associated pneumonia in patients admitted to the surgical intensive care unit

Design

A total of 90 patients admitted to the surgical intensive care unit who are eligible for inclusion in the study will be selected by convenience sampling method. Each participant will be assigned a code and will be randomly assigned into the intervention or control group.

Settings and conduct

This randomized controlled, triple-blinded clinical trial will be performed on patients admitted to the surgical and traumatic intensive care unit of Imam Reza Hospital in Birjand, who are diagnosed with ventilator-associated pneumonia 48 hours after mechanical ventilation. Information about the purpose of the study is explained to them and they will be assigned randomly into intervention or control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of ventilator-associated pneumonia after 48 hours of mechanical ventilation and informed consent for participation in the study. Major exclusion criteria: Pregnancy; infliction with pneumonia before intubation or 48 hours before intubation; and antibiotic use before intubation.

Intervention groups

Control group (routine): Individuals undergo antibiotic therapy and closed suction using a 50-cc normal sterile saline on a daily basis. Intervention group (bronchoscopic suction): Patients will undergo bronchoscopic suction every other day in addition to the treatment received by the control group.

Main outcome variables

Recovery based on Apache II criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N45**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-12, 1398/10/22**

Update count: **1**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of the routine procedure and the routine procedure supplemented by bronchoscopic suctioning in treating ventilator-associated pneumonia in patients admitted to the surgical intensive care unit

Public title

Impact of adding bronchoscopic suction to the routine therapy of pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of ventilator-associated pneumonia after 48 hours of mechanical ventilation Informed consent for participation in the study

Exclusion criteria:

Pregnancy Infection with pneumonia before intubation or 48 hours before intubation Antibiotic use before intubation Suffering from diseases that reduce immunity level Use of immunosuppressant drugs Patients with neutropenia (less than or equal to 500 neutrophils per milliliter)

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

The patients who are eligible to participate will be assigned a code. Afterward, the participants will be allocated to the intervention group or the control group using the table of random numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In addition to the participants themselves who are unaware of the intervention they receive, data collector and data analyzer are also both blinded to the allocated groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ayatollah Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2017-09-12, 1396/06/21

Ethics committee reference number

IR.BUMS.REC.1396.136

Health conditions studied

1

Description of health condition studied

ventilator-associated pneumonia

ICD-10 code

J12.8

ICD-10 code description

Other viral pneumonia

Primary outcomes

1

Description

Improvement status according to APACHI II criteria

Timepoint

daily

Method of measurement

APACHI II checklist

Secondary outcomes

1

Description

temperature

Timepoint

every 3 hours daily for a maximum of 10 days

Method of measurement

thermometer

2

Description

Number of blood leukocytes

Timepoint

on a daily basis

Method of measurement

laboratory results

3**Description**

Blood oxygenation status

Timepoint

on a daily basis

Method of measurement

arterial blood gas test

4**Description**

tracheal aspirate culture

Timepoint

at baseline and on completion day of study

Method of measurement

laboratory results

5**Description**

mortality

Timepoint

on a daily basis for 10 days

Method of measurement

observation

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

Control group (routine): Individuals undergo antibiotic therapy and closed suction using a 50-cc normal sterile saline on a daily basis.

Category

Treatment - Other

2**Description**

Intervention group (bronchoscopic suction): Patients will undergo bronchoscopic suction every other day in addition to the treatment received by the control group.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Maryam Bayati

Street address

ICU Ward, Imam Reza Hospital, Taleghani St.,

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Birjand,

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Xenon1346@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

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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

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Maryam Bayati

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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)

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

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

after the paper extracted from the study is published and for 6 months

To whom data/document is available

researchers

Under which criteria data/document could be used

research purposes

From where data/document is obtainable

email

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

email to the corresponding author

Comments