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)

Phone
+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 Infliction 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.,
City
Birjand,
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3222 2600
Email
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
Street address
Ghaffari St.,
City
Birjand,
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1200
Email
drtooba.kazem@gmail.com
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
Anethsesiology resident
Latest degree
Medical doctor
Other areas of specialty/work

Anesthesiology
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 32233019
Email
Xenon1346@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Hasan Karbasi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5600
Email
Xenon1346@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Bagher Roozgar
Position
Translator
Latest degree
Master
Other areas of specialty/work
Others
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5680
Fax
+98 56 3244 0447
Email
mbroozgar@bums.ac.ir

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