

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Inhaled Colistin on the Treatment of Pulmonary Infections Caused by Ventilator with Multi-drug Resistant Acinetobacter

Protocol summary

Summary

Objectives : Considering the importance and prevalence of ventilator-induced pulmonary infections in intensive care unit (ICU) patients, in this study we review the effect of adding inhaled colistin for the treatment of ventilator-associated pulmonary infection in ICU patients. **Design:** This study is a randomized controlled clinical trial in control and case groups. **Method:** The candidate patients with ventilator-induced pulmonary infections are randomly assigned to either placebo or interventional group. In the intervention group, patients received 150 mg colistin plus 1,000,000 unit nebula every eight hours and the control group received only 300 mg every eight hours. Using clinical pulmonary infection score (CPIS), patients are followed up for seven days after the initial diagnosis in terms of clinical findings such as body temperature, white blood cell count, pulmonary secretion culture, and chest radiograph status. **Inclusion criteria:** This study performed on 114 patients with ventilator-induced pulmonary infections (VAP) admitted to the ICU of Rasoul-e-Akram Hospital Complex after obtaining informed consent. Patients over 16 years of age entered the study with multi-drug resistant (MDR) Acinetobacter, positive culture and without sensitivity to polymyxins. **Exclusion criteria:** Patients were excluded due to death, having sensitivity to polymyxin, a decrease in GFR of <0.25 or the occurrence of evidence of bronchospasm in the intervention group. **Main outcome measures:** The response to treatment is considered for normalization of all CPIS criteria and improving the CPIS score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091236068N1**

Registration date: **2017-11-15, 1396/08/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-15, 1396/08/24

Registrant information

Name

Behnam Mahmoudyeh

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2675 8928

Email address

b.mahmodie@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

There was no funding source in this study.

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Inhaled Colistin on the Treatment of Pulmonary Infections Caused by Ventilator with Multi-drug Resistant Acinetobacter

Public title

Effect of Inhaled Colistin on the Treatment of Pulmonary Infections Caused by Ventilator with Multi-drug Resistant Acinetobacter at in Intensive Care Unit of Rasoul-Akram

Hospital in 2016-17

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age ranging: over 16 years; multi-drug resistant patients especially multidrug-resistant Acinetobacter; without sensitivity to polymyxins; positive culture (Colony count: BAL 104 or Mini BAL 105).
Exclusion criteria: patient death; incidence of sensitivity to polymyxins; reduced GFR <0.25; incidence of bronchospasm evidences in treatment group.

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Ethics Committee of Iran University of Medical Sciences, Iran University of Medical Sciences, Hemmat Highway, Tehran, Tehran Province

City

Tehran

Postal code

Approval date

2017-06-06, 1396/03/16

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9211384201

Health conditions studied

1

Description of health condition studied

Pulmonary infection Caused by Ventilator

ICD-10 code

A31.0

ICD-10 code description

Pulmonary mycobacterial infection

Primary outcomes

1

Description

The severity of pulmonary infection using CPIS

Timepoint

At the first, third and seventh days after intervention

Method of measurement

Using Clinical Pulmonary Infection Score (CPIS)
Calculator; CPIS more than 6 at baseline or at 72 h: pneumonia; CPIS less or equal to 6 at 72 hours patient: without pneumonia

Secondary outcomes

empty

Intervention groups

1

Description

In treatment group, patients received administrated 150 mg of intravenous colistin in addition to 1000000 units inhaled colistin for one week every eight hours.

Category

Treatment - Drugs

2

Description

The control group only received 300 mg of colistin every eight hours intravenously for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram hospital

Full name of responsible person

Dr Behnam Mahmoudyeh

Street address

Rasoul-e-Akram hospital, Satarkhan St, Tehran, Tehran Province

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology of Iran
University of Medical Sciences

Full name of responsible person

Dr Sayed Ali javad Mousavi

Street address

Vice chancellor for Research and Technology of Iran
University of Medical Sciences, Iran University of
Medical Sciences, Hemmat Highway, Tehran, Tehran
Province

City

Tehran

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 and Technology of Iran
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Arak University of Medical sciences , Iran

Full name of responsible person

Dr Behnam Mahmoudyeh

Position

Anesthesiologist

Other areas of specialty/work**Street address**

Department of Anesthesiology, Valiasr Hospital,
ValiAsr Square, Arak

City

Arak

Postal code**Phone**

+98 21 2675 8928

Fax**Email**

behnammahmoudye@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical sciences , Iran

Full name of responsible person

Dr Behnam Mahmoudyeh

Position

Anesthesiologist

Other areas of specialty/work**Street address**

Department of Anesthesiology, Valiasr Hospital,
ValiAsr Square, Arak

City

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Fax**Email**

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Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Arak University of Medical sciences , Iran

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Dr Behnam Mahmoudyeh

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behnammahmoudye@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty