

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of colistin / levofloxacin in comparison with colistin / meropenem in the treatment of ventilator-associated pneumonia (VAP) induced by carbapenem-resistant *Acinetobacter baumannii*: a randomized, controlled clinical trial

Protocol summary

Study aim

1. Determining the number of treatments, clinical improvement and treatment failure (clinical response) in the experimental group after treatment 2. Determining the number of treatments, clinical improvement and treatment failure (clinical response) in the control group after treatment 3. Comparison 1 and 2 4. Determining the number of cases of microbial eradication and microbial failure (microbiological response) in the experimental group after treatment Determining the number of other microbial cases and microbial failure (microbiological response) in the control group after treatment 6. Compare 4 and 5 7. Determining the index of clinical score of lung infection (clinical score of lung infection [CPIS]) in the experimental group before and after the intervention

Design

Two arm parallel group randomized controlled clinical trial. Online randomization program will be used for randomization.

Settings and conduct

This study will be a randomized and controlled clinical trial. Patients are selected from the intensive care unit (ICU) of Al-Zahra, Amin and Ayatollah Kashani hospitals in Isfahan. Adults with ventilator-associated pneumonia (VAP) are evaluated for inclusion in the study.

Participants/Inclusion and exclusion criteria

Age over 18 years Under mechanical ventilation (intubation) for more than 48 hours VAP diagnosis Growth of carbapenem-resistant *Acetobacter baumannii* (Meropenem) in culturing lung secretions

Intervention groups

Experimental group: colistin (4.5 MU IV q12h) + levofloxacin (750 mg IV q24h) Control group: colistin (4.5 MU IV q12h) + meropenem (1 g IV q8h)

Main outcome variables

Clinical response (cure, improvement, or failure) CPIS score;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N17**

Registration date: **2021-05-12, 1400/02/22**

Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**

Update count: **0**

Registration date

2021-05-12, 1400/02/22

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

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soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-08-26, 1401/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of colistin / levofloxacin in comparison with colistin / meropenem in the treatment of ventilator-associated pneumonia (VAP) induced by carbapenem-resistant *Acinetobacter baumannii*: a randomized, controlled clinical trial

Public title

Comparison of colistin / levofloxacin combination with colistin / meropenem combination in the treatment of ventilator-dependent upper respiratory tract (VAP) induced by *Acinetobacter*: a randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Under mechanical ventilation (intubation) for more than 48 hours VAP diagnosis Growth of carbapenem (meropenem)-resistant *Acinetobacter baumannii* in the lung secretions culture

Exclusion criteria:

Pregnancy Lactation Sensitivity to meropenem, colistin, or levofloxacin Acute Respiratory Distress Syndrome Active pulmonary tuberculosis

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was used for patients' allocation to the groups. For this, an online random number generator is used (available at: <https://www.random.org/sequences>) so that even and odd numbers will be considered for experimental and placebo groups, respectively, and each patient, after inclusion, will be assigned to the related group according to the determined sequence.

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 Isfahan University of Medical Sciences

Street address

Hezar-Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

خیابان هزار جریب

Approval date

2020-12-09, 1399/09/19

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.606

Health conditions studied**1****Description of health condition studied**

Ventilator-induced pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes**1****Description**

Clinical Response (defined as cure or improvement or treatment failure)

Timepoint

End of intervention

Method of measurement

Clinical judgment by the observation of the patient

Secondary outcomes**1****Description**

Clinical Pulmonary Infection Score (CPIS)

Timepoint

Before and after the intervention

Method of measurement

Questionnaire

2**Description**

Mortality rate during the intervention
Timepoint
The end of intervention
Method of measurement
Counting

Intervention groups

1

Description
Experimental group: colistin (4.5 MU IV q12h) +
levofloxacin (750 mg IV q24h), for 10 days
Category
Treatment - Drugs

2

Description
Control group: colistin (4.5 MU IV q12h) + meropenem (1
g IV q8h), for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital; Amin Hospital of Isfahan; Kashani
Hospital
Full name of responsible person
Dr. Rasool Soltani
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Isfahan, Sefeh St., Al-Zahra Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
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Hezar-Jerib Avenue, Isfahan University of Medical
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
Associate professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

En Confidentiality of patients data

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