

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the effectiveness of colistin / rifampin compared to colistin / meropenem in the treatment of ventilator-associated pneumonia (VAP) due to 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) + rifampin (300 mg PO q12h)
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: **IRCT20150721023282N22**

Registration date: **2022-07-24, 1401/05/02**

Registration timing: **prospective**

Last update: **2022-07-24, 1401/05/02**

Update count: **0**

Registration date

2022-07-24, 1401/05/02

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of colistin / rifampin compared to colistin / meropenem in the treatment of ventilator-associated pneumonia (VAP) due to carbapenem-resistant *Acinetobacter baumannii*: a randomized, controlled clinical trial

Public title

Comparison of colistin / rifampin 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

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Hezar-Jerib Ave

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8174673461

Approval date

2022-07-02, 1401/04/11

Ethics committee reference number

IR.MUI.MED.REC.1401.146

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 - Clinical Pulmonary Infection Scoring System

2

Description

Mortality rate during the intervention

Timepoint

The end of intervention

Method of measurement

Counting

Intervention groups

1

Description

Intervention group: colistin (Product of Exir pharmaceutical company , 4.5 MU IV q12h) + rifampin (Product of Hakim Pharmaceutical Company , 300 mg PO q12h), for 10 days

Category

Treatment - Drugs

2

Description

Control group: colistin (Product of Exir pharmaceutical company , 4.5 MU IV q12h) + meropenem (Product of Exir pharmaceutical company ,1 g IV q8h), for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Dr. Rasool Soltani

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Recruitment center

Name of recruitment center

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3

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

professor

Latest degree

Specialist

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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