Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
Isfehan
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

Street address

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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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

Specialist

Other areas of specialty/work

Medical Pharmacy

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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