

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effects of Meropenem, intravenous Colistin plus nebolized Colistin and Meropenem, intravenous Colistin plus nebolized Granulocyte Colony Stimulating Factor(G-CSF) on treating patients with Ventilator Associated Pneumonia (VAP) due to multidrug_resistance Acinetobacter

Protocol summary

Study aim

Effect of nebolized G-CSF in treatment of VAP due to MDR Acinetobacter

Design

Two arm parallel group randomised trial with blinded postoperative care and outcom assessmen.In this study 60 paitients VAP due to MDR Acinetobacter were selected base on inclusion and exclusion criteria for participation ,then they were randomly assigned to two groups of 30 people

Settings and conduct

Alzahra Hospital of Isfahan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Mechanical ventilation more than 48 hours, Multidrug rsistance Acinetobacter in tracheal culture, Satisfaction with the first class family Exclusion critera: Allergy to colistin, other infections

Intervention groups

Intervention group1: In group, patients that received Meropnem 2 gr every 8 hours, interavenous Colistin 4.5 million international units(IU) every 12 hours and nebulized Colistin 4.5 (IU) every 12 hours daily for a period of 14 days then CPIS was determined at days 1,3,5,7,14
Intervention group2: In group, patients that received Meropnem 2 gr every 8 hours, interavenous Colistin 4.5 (IU) every 12 hours and nebulized G-CSF with the dose of 150 microgram every 48 hours for 14 days then CPIS was determined at days 1,3,5,7,14

Main outcome variables

CPIS score, achievement in treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150824023743N2**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**

Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Farzin Khorvash

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 313792900698

Email address

khovash@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2018-04-21, 1397/02/01

Trial completion date

2018-04-21, 1397/02/01

Scientific title

Comparison the effects of Meropenem, intravenous Colistin plus nebulized Colistin and Meropenem, intravenous Colistin plus nebulized Granulocyte Colony Stimulating Factor(G-CSF) on treating patients with Ventilator Associated Pneumonia (VAP) due to multidrug_resistance Acinetobacter

Public title

Effect of nebulized G-CSF in treatment of Ventilator Associated Pneumonia (VAP)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Mechanical ventilation more than 48 hours Multidrug resistance Acinetobacter in tracheal culture Satisfaction with the first class family

Exclusion criteria:

Allergy to Colistin Other infections

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Using block randomization

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2018-10-04, 1397/07/12

Ethics committee reference number

IR.MUI.MED.REC.1397.052

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

Ventilator associated pneumonia

ICD-10 code

B99-B99

ICD-10 code description

other infectious diseases

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

Achieve in treatment

Timepoint

1,3,5,7 and 14 days after intervention

Method of measurement

Calculate the Clinical Pulmonary Infection Score table

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this group patients that received Meropenem (Dana company) 2g every 8 hour , injectable Colistin (Exir company) 4.5 million IU every 12 hour, plus nebulized G-CSF(Sinagen company) with the dose of 150 microgram every 48h for 14 days.

Category

Treatment - Drugs

2**Description**

Control group: In this group patients that received Meropenem (Dana company) 2 gr every 8 hours, injectable Colistin (Exir company) pluse nebulized Colistin 4.5 million units every 12 hours for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital of Isfahan

Full name of responsible person

Fatemeh Mohajeri

Street address

Alzahra Hospital, Soffeh Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

mohajerifatemeh4@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Mohajeri

Street address

Isfahan Univresity of Medical Scinces, Hezar Jerib Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

mohajerifatemeh4@gmail.com

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

Fatemeh Mohajeri

Position

Assistant, infectious diseases and tropical medicine research center

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

Isfahan University of Medical Science, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

mohajerifatemeh4@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable