

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the effects of Meropenem,intravenous Colistin plus nebolized Colistin and Meropenem,intravenous Colistin plus nebolized Tubramycin on treating patients with ventilator associated pneumonia (VAP) due to multidrug_resistance Acintobacter

Protocol summary

Study aim

Effect of nebolized Tubramycin in treatment of Ventilator Associated Pneumonia(VAP) due to Acintobacter multidrug resistance(MDR)

Design

Two arm parallel group randomised trial with blinded postoperative care and outcom assessmen.In this study 60 patients VAP due to Acintobacter MDR were selected based on inclusion and exclusion criteria for participation in this study ,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 intubation more than 48 hours,Acintobacter MDR in tracheal culture and satisfaction with the first class family Exclude criteria : Age under 18 years , Allergy to Colistin,other diseases

Intervention groups

Intervention group 1 : In this group, patients recieved Meropenem 2g every 8 hours,injectable colistin 4/5 million IU every 12 hours plus nebolized Colistin 4/5 million IU every 12 hours for the period of 14 days.then CPIS was determined on days 1 , 3 , 5 , 7 , 14.

Intervention group 2 :In this group, patients recieved Meropenem 2g every 8 hours, injectable colistin r/5 million IU every 12 hours plus nebolized Tubramycin 300mg every 12 hours for the period of 14 days.then CPIS was determined on days 1 , 3 , 5 , 7 , 14

Main outcome variables

CPIS score, achivement in treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150824023743N3**

Registration date: **2019-12-31, 1398/10/10**

Registration timing: **retrospective**

Last update: **2019-12-31, 1398/10/10**

Update count: **0**

Registration date

2019-12-31, 1398/10/10

Registrant information

Name

Farzin Khorvash

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 313792900698

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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 nebolized Colistin and Meropenem,intravenous Colistin plus nebolized Tubramycin on treating patients with ventilator associated pneumonia (VAP) due to multidrug_resistance Acintobacter

Public title

Effect of nebolized Tubramycin in treatment of ventilator associated pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Mechanical ventilator more than 48 hours Multidrug_resistance Acintobacter in tracheal cultures 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.since two groups of patients are needed for this study,six different blocks of 4 were considered and random number table was used to randomly place the numbers on the table and to move btween two numbers.select up and finally determined the order of the path blocks based on the order of these numbers.in this study,the order of the blocks was 3,5,6....finally 15 blocks of 4 were identified and the order of TCTC and then TCCT and...by doing this process,the patients were divided into two equal groups of intervention and control groups randomly.

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

2017-12-20, 1396/09/29

Ethics committee reference number

IR.MUI.REC.1396.3.768

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonis

ICD-10 code

B99-B99

ICD-10 code description

Other infectious disease

Primary outcomes

1

Description

Clinical pulmunaary infection score

Timepoint

1 , 3 , 5 , 7 and 14 after intervention

Method of measurement

Calculate the clinical pulmunaary infection score table

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group recieved Meropenem(Dana company) 2g every 8 hour , injectable Colistin(Exir company) 4/5 million IU every 12 hours , plus nebolized Tubramycin 300 mg every 12 hours for 14 days.

Category

Treatment - Drugs

2

Description

Control group: This group received Meropenem (Dana company) 2g every 8 hours, injectable Colistin (Exir company) 4/5 million IU every 12 hours, plus nebulized Colistin 4/5 million IU 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

Shoeleh yaghoubi

Street address

Alzahra hospital , Soffeh Avenue , Isfahan

City

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8174675731

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+98 31 5555 3668

Email

Sholeyaqubi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Rasoul Roknizade

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Isfahan University of medical science , Hezar Jerib Avenue , Isfahan

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Esfahan University of Medical Science

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

Shoeleh Yaghoubi

Position

Assistant , infectious diseases and tropical medicine research center

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Latest degree

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Position

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Latest degree

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Other areas of specialty/work

Infectious disease

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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