

# 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)

##### 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 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**

Isfahan

**Province**

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**Postal code**

8174675731

**Phone**

+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

**Street address**

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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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