

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of efficacy of Colistin IV, Colistin Nebulized with Colistin IV, Meropenem in the treatment of ventilator associated pneumonia caused by MDR gram negative microorganisms, a randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of efficacy and safety of Colistin IV/Colistin nebulized and colistin IV/Meropenem in the treatment of pneumonia caused by gram negative MDR bacteria

##### Design

This is an open-label randomized clinical trial. Patients will be equally assigned to any of the groups according to permuted block randomization method.

##### Settings and conduct

Patients of intensive care units of Imam Khomeini Hospital Complex with the inclusion criteria, will be randomly assigned to either the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion: Diagnosis of ventilator-associated pneumonia; clinical symptoms of pneumonia occurred after 24-48 hours of intubation, along with a positive endotracheal aspirate culture Exclusion: Previous untreated pneumonia, age of less than 16 years, a sensitive antibiogram, a history of allergy to carbapenems and or colistin

##### Intervention groups

Group1:Colistin 9MIU loading dose as iv infusion over 1 hour then 4.5MIU every 12 hour as iv infusion over 1 hour + Meropenem 2g every 8 hour as iv infusion over 3 hours for at least 7 days Group2: Colistin 9MIU loading dose as iv infusion over 1 hour then 4.5MIU every 12 hour as iv infusion over 1 hour + Nebulized colistin 2 MIU every 8 hour using jet nebulizer for at least 7 days (Dose adjustments will be done according to patient's renal states)

##### Main outcome variables

Clinical improvement of pneumonia

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190616043906N1**

Registration date: **2020-03-01, 1398/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

#### Registration date

2020-03-01, 1398/12/11

#### Registrant information

##### Name

Sepideh Goudarzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

s-goudarzi@student.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-01-12, 1398/10/22

#### Expected recruitment end date

2021-01-11, 1399/10/22

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of efficacy of Colistin IV, Colistin Nebulized with Colistin IV, Meropenem in the treatment of

ventilator associated pneumonia caused by MDR gram negative microorganisms, a randomized clinical trial

#### Public title

Nebulized colistin in pneumonia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Diagnosis of pneumonia 48 hours after intubation (radiographical, laboratory and clinical findings along with a positive tracheal aspirate culture)

##### Exclusion criteria:

Signs of previous pneumonia at the time of intubation No concomitant antibiotics indicated to treat pneumonia other than the study (but allowed for other infections) Patients with a positive culture but no clinical and radiological findings for pneumonia An antibiogram sensitive to any antibiotics else than polymyxins Any history of allergy and seizure caused by Carbapenems/Colistin

#### Age

From **16 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **42**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization will be done according to the blocks randomization method. In accordance with the sample size, seven blocks will be chosen. Random sequences will be created by SAS software.

#### 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 Tehran University of Medical Sciences

###### Street address

Ghods street

###### City

Tehran

###### Province

Tehran

###### Postal code

1417653761

###### Approval date

2020-01-12, 1398/10/22

###### Ethics committee reference number

IR.TUMS.VCR.REC.1398.800

### Health conditions studied

#### 1

##### Description of health condition studied

Ventilator-associated pneumonia

##### ICD-10 code

J15.0

##### ICD-10 code description

Pneumonia due to Klebsiella pneumoniae

### Primary outcomes

#### 1

##### Description

Clinical response of pneumonia to the treatment regimen

##### Timepoint

Days 2 and 7

##### Method of measurement

Evaluating vital signs, oxygenation, laboratory and hemodynamic parameters

#### 2

##### Description

Incidence of acute kidney injury

##### Timepoint

Days 2 and 7

##### Method of measurement

According changes in serum creatinine levels and urine volume

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Colistin 9MIU loading dose as iv infusion over 1 hour then 4.5MIU every 12 hour as iv infusion over 1 hour + Colistin nebulized 2 MIU every 8 hour using jet nebulizer for at least 7 days

##### Category

Treatment - Drugs

#### 2

##### Description

Colistin 9MIU loading dose as iv infusion over 1 hour then 4.5MIU every 12 hour as iv infusion over 1 hour+ Meropenem 2g every 8 hour as iv infusion over 3 hours for at least 7 days

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital Complex

**Full name of responsible person**

Hossein Khalili

**Street address**

Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 2756

**Email**

Khalilih@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraian

**Street address**

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8898 7381

**Email**

msahrai@sina.tums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khalili

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical Pharmacy

**Street address**

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614411

**Phone**

+98 21 6658 1598

**Email**

khalilih@tums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khalili

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical pharmacy

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**Email**

khalilih@tums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sepideh Goudarzi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614411

**Phone**

+98 21 6695 4709

**Fax****Email**

s-goudarzi@student.tums.ac.ir

**Web page address****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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

Results of the study will be published. The study protocol and statistical analysis will be included in the article.

**When the data will become available and for how long**

One year after the end of the study, data will be published and will be available in databases.

**To whom data/document is available**

After permission from the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes.

**Under which criteria data/document could be used**

Other researchers are permitted to include the results in their systematic reviews and meta-analysis upon citing the original article.

**From where data/document is obtainable**

For this you may ask Hossein Khalili through following information: Address: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

**What processes are involved for a request to access data/document**

After receiving the query, depending on the type of requested data, the person responsible for scientific issues of the study will respond to the query within 2 weeks, after an agreement with the sponsor.

**Comments**