

# 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

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Keshavarz Blvd.

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1419733141

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**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

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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

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**Province**

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**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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**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

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**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**