

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of High Doses of Meropenem with its Usual Dose in increasing the effect of Cholestine on the treatment of ventilator-dependent pneumonitis resulting from Acinetobacter

#### Protocol summary

##### Study aim

Comparison of the effectiveness of high dose of meropenem with its usual dose in increasing the effect of cholestine on the treatment of ventilator-dependent pneumonia caused by Acinetobacter

##### Design

The study was a double-blind clinical trial in two intervention groups (continuous infusion of 250 mg per hour) and a control group (one gram every 8 hours) with a sample size of 60 people over 6 months.

##### Settings and conduct

The study is a double-blind clinical trial in the ICU of Imam Hossein Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

1. Age over 18 years 2. Having at least two VAP(Ventilation Associated Pneumonia) criteria

##### Intervention groups

The intervention group will be given a 250 mg dose of Meropenem ampule by continuous infusion with a pump. The control group will be given an intravenous dose of Meropenem ampule at a usual dose of 1000 mg every 8 hours. Both will be routinely treated with coeistine. Evaluation of VAP(Ventilation Associated Pneumonia) criteria will be performed daily in both groups and the response to the drug in both intervention and control groups will be compared. The study is double blind. The medicine is prescribed by a doctor and injected and recorded by a nurse. The samples will be analyzed by the center's laboratory expert. The interpretation of the data will be done by the researcher and will be decided based on the interpreted results.

##### Main outcome variables

Ventilator Associated Pneumonia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210405050848N1**  
Registration date: **2021-06-07, 1400/03/17**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-07, 1400/03/17**

Update count: **0**

##### Registration date

2021-06-07, 1400/03/17

##### Registrant information

##### Name

Jafar Vakili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3351 5720

##### Email address

jafar.vakili@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-20, 1400/02/30

##### Expected recruitment end date

2021-11-21, 1400/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of High Doses of Meropenem with its Usual

Dose in increasing the effect of Cholestine on the treatment of ventilator-dependent pneumonitis resulting from Acintobacter

**Public title**

Pneumonia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 18 years Having at least two VAP criteria (increase in WBC above 11000 and decrease in WBC below 4000, fever above 38.5, culture of pulmonary secretions sensitive to cleistine, changes in CXRay)

**Exclusion criteria:**

History of allergy to Meropenem

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After entering the participants according to the inclusion criteria, the pretest was performed using a ventilator-dependent pneumonia evaluation checklist, then randomly assigned by the head nurse based on blocking. Given that 60 people had to be included in the study and there were two groups (intervention and control), taking into account all possible possibilities, 6 blocks of 4 states were calculated (it is necessary to explain that the number of blocks of the combination formula :  $C(n, r) = \frac{n!}{r!(n-r)!}$  was obtained).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study is double blind. The drug is prescribed by a physician and injected by a nurse and recorded in a checklist. The patient and the researcher have no role in randomly assigning the samples to the intervention or control group, and the intervention will be performed and the results will be recorded by the relevant nurse. The samples will be analyzed by the center's laboratory expert. The interpretation of the data will be done by the researcher and will be decided based on the interpreted results.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shahid beheshti University of Medical Sciences

**Street address**

th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2021-03-06, 1399/12/16

**Ethics committee reference number**

IR.SBMU.MSP.REC.1399.772

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

Pneumonia

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

VAP (Ventilation Associated Pneumonia)caused by Acinetobacter

**Timepoint**

Before and 3 day After intervention

**Method of measurement**

VAP(Ventilation Associated Pneumonia) criteria

**Secondary outcomes****1****Description**

control of ventilator associated pneumonia

**Timepoint**

Before and 3 days after intervention

**Method of measurement**

VAP (Ventilation Associated Pneumonia) criteria

## Intervention groups

### 1

#### Description

Intervention group: Continuous infusion of Meropenem(The intervention group will be given a 250 mg dose of Meropenem ampule as a continuous infusion with a pump, and routine infusion of Cleistine will continue in ventilator-associated pneumonia.)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Infusion each 8 hours of Meropenem (The control group will receive an intravenous infusion of Meropenem at a dose of 1000 mg every 8 hours. Routine infusion of Cleistine will continue in ventilator-associated pneumonia.)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Hosein Hospital

##### Full name of responsible person

Jafar Vakili

##### Street address

Emam Hossein Hosp. Madani St. Tehran Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Fax

+98 21 23871

##### Email

jafar.vakili@sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Afshin Zargi

##### Street address

7th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

##### City

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1983963113

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##### Email

jafar.vakili@sbm.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Jafar Vakili

##### Position

Fellowship of ICU

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

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7th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Other areas of specialty/work**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available