

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

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Fax

+98 21 2243 9770

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

jafar.vakili@sbm.ac.ir

Person responsible for scientific 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

jafar.vakili@sbmu.ac.ir

Person responsible for updating data**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

Street address

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

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9770

Email

jafar.vakili@sbmu.ac.ir

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