Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effect of amikacin in the prevention of ventilator-induced pneumonia in patients admitted ICU

Protocol summary

Study aim
The effect of inhaled amikacin in preventing ventilator-induced pneumonia in patients hospitalized in ICUs of Valiasr Hospital is being investigated

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 126 patients. Block method was used for randomization.

Settings and conduct
Intensive care units of Arak Valiasr hospital The present study will be a double-blind clinical trial study. Patients were randomized by block method and will be divided into two groups in the form of 4 blocks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 years or older, absence of lung disease and lung mass, absence of chemotherapy drugs, absence of enteral nutrition, absence of antibiotics before the start of VAP, absence of kidney disease and chronic failure Kidney with basic glomerular filtration of less than 30 ml per minute, the patient's tracheal tube not coming out within the next 48 hours after implantation, the absence of pregnant or lactating women, GFR greater than 50, lack of sensitivity to amikacin, absence of myasthenia gravis, Absence of covid 19 (PCR negative) Exclusion criteria: patients who require mechanical ventilation for less than 48 hours (because the risk of VAP in them is low), lack of consent to participate in the study by the guardian, re-intubation, if gfr decreases by more than 20% within 48 hours Amikacin is discontinued

Intervention groups
Patients requiring mechanical ventilation in the intensive care unit

Main outcome variables
Duration of mechanical ventilation, duration of hospitalization in the ICU, mortality, incidence of early-onset pneumonia and Late onset pneumonia, GFR index, CPIS criterion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220702055337N1**
Registration date: **2022-09-16, 1401/06/25**
Registration timing: **prospective**

Last update: **2022-09-16, 1401/06/25**
Update count: **0**

Registration date
2022-09-16, 1401/06/25

Registrant information

Name
Zahra Ourang

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-21, 1401/06/30

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of amikacin in the prevention of ventilator-induced pneumonia in patients admitted ICU

Public title
The effect of amikacin in the prevention of ventilator-induced pneumonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 and above Absence of lung disease and lung mass No use of chemotherapy drugs Absence of intestinal nutrition No receiving of Antibiotics before the onset of VAP Absence of kidney disease and chronic kidney failure with basic glomerular filtration less than 30 ml in minutes No removing the patient's tracheal tube within the next 48 hours after insertion Lack of sensitivity to amikacin Absence of Myasthenia gravis Not pregnant or Lactating Absence of covid-19 disease (negative PCR) GFR more than 50
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into two groups by block method in the form of blocks of 4. Blocking and allocation sequence will be done by a person not involved in the research, and they will be in two groups receiving amikacin antibiotic and control. Then, based on the obtained blocks and according to the allocation sequence, the medicine will be given to the patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
According to the double blind study, in this study the patients and also the data analyst and the intern of the project partner who is responsible for completing the questionnaires will be unaware of the division
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of medical science,Sardasht
City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۴۵
Approval date
2022-09-11, 1401/06/20
Ethics committee reference number
IR.ARAKMU.REC.1401.139

Health conditions studied

1

Description of health condition studied
Pneumonia
ICD-10 code
J95.851
ICD-10 code description
Ventilator associated pneumonia

Primary outcomes

1

Description
Early and late onset pneumonia
Timepoint
14 days from beginning
Method of measurement
CPIS checklist

2

Description
Mortality
Timepoint
14 days
Method of measurement
Checklist

3

Description
Ventilator time
Timepoint
14 days
Method of measurement
Checklist

4

Description
ICU hospitalisation
Timepoint
14 days
Method of measurement
Checklist

5

Description
Glomerular filtration rate
Timepoint
Every day for 14 days
Method of measurement
GFR formula

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who undergo invasive ventilation for more than 3 days are randomly divided into two groups: Intervention group: amikacin powder without sulfite (Caspian Pharmaceuticals, Tamin, Iran) in sterile water (1 gram per 8 ml) liter) will be dissolved and inhaled once a day for 3 days at a dose of 20 mg/kg based on the estimated body weight.
Category
Treatment - Drugs

2

Description
Control group: plasbo inhalation (0.9% sodium chloride) is used by inhalation daily for 3 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Intensive care unit of Valiasr hospital
Full name of responsible person
Zahra Ourang
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr.Aliraza Kamali
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Zahra Ourang
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available