

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)

Phone

+98 86 3223 4861

Email address

pz.ourang@gmail.com

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: placebo 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

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Valiasr Sq, Imam Khomeini St

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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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Person responsible for updating data

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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