

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Prophylactic antibiotic for Early Ventilator associated Pneumonia in stroke Patients

Protocol summary

Summary

In this clinical trial, 84 patients (male or female) with stroke and 20 years or older admitted to the neurology intensive care unit of Valiasr hospital will be enrolled based on inclusion and exclusion criteria. The demographic data including age, sex, underlying disease and the admission form will be recorded for each patient. The severity of illness will be assessed by using APACHE score. Written informed consent from the patient's Legal guardian will be obtained. The patients will be divided randomly into two equal groups. Patients in the combination piperacillin - tazobactam dose 4.5 g (piperacillin 4 g and tazobactam 0.5 g) coincides with intubation and then 12 hours later, will receive the control group received normal saline solution likewise. Then the process would be similar between the two groups. Finally the incidence of early ventilator associated pneumonia in patients in both groups as the primary outcome and duration of admission, early ventilator associated pneumonia and rate of mortality as a secondary outcome of this study will be discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407029855N6**

Registration date: **2014-07-21, 1393/04/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-21, 1393/04/30

Registrant information

Name

Aiasghar Farazi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.farazi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic antibiotic for Early Ventilator associated Pneumonia in stroke Patients

Public title

Prophylactic antibiotic in ventilator associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age over 20 years; Glasgow scale of less than 9, less than 12 hours of mechanical ventilation passed; at least 48 hours under of mechanical ventilation. Exclusion criteria: patients who admitted 48 hours before intubation in hospital; patients who received more than two doses of antibiotics before intubation; Patients who have need antibiotics for any

reason; patients who are candidates for organ donation; patients with immunodeficiency; patients who are allergic to piperacillin-tazobactam.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

School of Medicine, Sardasht, Arak

City

Arak

Postal code

Approval date

2014-03-16, 1392/12/25

Ethics committee reference number

92-157-8

Health conditions studied

1

Description of health condition studied

Ventilator Associated Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

Primary outcomes

1

Description

Early ventilator associated pneumonia

Timepoint

Days 1,2,3,4

Method of measurement

Chest X ray, clinical signs, microbiological study

Secondary outcomes

1

Description

Late ventilator associated pneumonia

Timepoint

Days 5 , 7, 10 , 14

Method of measurement

Chest X ray, clinical sign and Microbiology study

2

Description

Mortality report

Timepoint

Daily to two weeks

Method of measurement

Reviewing date of death

3

Description

Length of stay in ICU

Timepoint

Daily to two weeks

Method of measurement

Reviewing date of discharge

Intervention groups

1

Description

Patients in the case group receive intravenous piperacillin - tazobactam 4.5 g (piperacillin 4 g and tazobactam 0.5 g) simultaneously with intubation and then 12 hours after intubation and simultaneously receive subsequent treatment that was similar in both groups.

Category

Prevention

2

Description

Patients in the control group receive intravenous normal saline simultaneously with intubation and then 12 hours after intubation and simultaneously receive subsequent treatment that was similar in both groups.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital in arak

Full name of responsible person

Dr.Aliasghar Farazi

Street address

Department of infectious diseases, Valiasr hospital,
Arak Arak Markazi Iran, Islamic Republic Of

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpoo

Street address

School of Medicine, Sardasht, Arak

City

Arak

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. aliasghar Farazi

Position

Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty