

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison three methods in prevention Ventilator-Associated Pneumonia in intensive care unit

Protocol summary

Study aim

Evaluation of three methods in prevention Ventilator-Associated Pneumonia in intensive care unit

Design

This study is clinical trial and double blind. 201 patients in ICU ward in Valiasr hospital in arak city enter this study. We will divide patients in 3 groups.

Settings and conduct

This study is clinical trial and double blind. 201 patients in ICU ward in Valiasr hospital in arak city will enter. We will divide patients in 3 groups by random number table. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All persons with intubation in intensive care unit of Valiasr hospital, both sexes
Exclusion criteria: Dissatisfied to participate in the study

Intervention groups

Group A: VAP Bundle and personnel hand wash (before each action for the patient) and frequent suction of discharge at least every 6 hours and for every case
Group B: Bundle VAP and personnel regular hand washing procedures (before each intervention for the patient) and oral mucosal cleaning with chlorhexine 0.12 percent for 2 times a day, and at frequent suctioning of the secretions at least every 6 hours and for every case.
Group C: Bundle VAP and personnel hand washing and mouth washing of patients with chlorhexidine 0.12 percent and closed suction every 6 hours and case.

Main outcome variables

Frequency of ventilator-associated pneumonia, duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N116**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **retrospective**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison three methods in prevention Ventilator-Associated Pneumonia in intensive care unit

Public title

Comparison three methods in Pneumonia in intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All intubated patients in intensive care units of Valiasr hospital Both sexes

Exclusion criteria:

No consent to participate in the study

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **201**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in three groups A and B and C. In this method, we selected a number of cards or letters as an intervention group1 and the same number of cards for intervention group 2 and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome assessor and analyzer don't aware from grouping. Groups A and B and C are available to analyzer and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2017-10-08, 1396/07/16

Ethics committee reference number

IR.ARAKMU.REC.1396.106

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

Ventilator associated pneumonia

Timepoint

after 48 hours

Method of measurement

Phlegm cultures

2

Description

Duration of hospitalization

Timepoint

After intervention

Method of measurement

day

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: VAP Bundle and personnel hand wash (before each action for the patient) and frequent suction of discharge at least every 6 hours and for every case

Category

Prevention

2

Description

Intervention group: Bundle VAP and personnel regular hand washing procedures (before each intervention for the patient) and oral mucosal cleaning with chlorhexine 0/12 percent for 2 times a day, and at frequent suction of discharge at least every 6 hours and for every case

Category

Prevention

3

Description

Intervention group: Bundle VAP and hand washing in personnel and mouth washing of patients with chlorhexidine 0/12 percent and closed suction every 6 hours and case.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Nader Zarinfar

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3417 3645

Fax

+98 86 3222 2003

Email

zarinfar@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Vice Chancellor For Research, Arak University Of
Medical Science

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

arjmandzadegan@arakmu.ac.ir

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

Dr Behnam Mahmodie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mahmodie@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Nader Zarinfar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Arak, Valiasr Hospital

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

zarinfar@arakmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Azita Reihani

Position

Resident of infection

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

Payambar Azam Complex, Basij square, Sardasht,
Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

reihani@gmail.com

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Zarinfar

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments