

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of selective oral decontamination regimen and chlorhexidine on rate of ventilator-associated pneumonia in patients admitted to the intensive care unit care of Beheshti hospital in Kashan 2023

Protocol summary

Study aim

Determining the effect of selective oral decontamination regimen and chlorhexidine on rate of ventilator-associated pneumonia

Design

A community-based, pragmatic, control group clinical trial, randomized with parallel groups.

Settings and conduct

Intervention in the first group: Patients will receive 2% chlorhexidine mouthwash every 6 hours for 4 days. In the second intervention group: patients will receive mouthwash with SOD solution by the researcher in the special care department at the same time as the previous group. Then, ventilator-associated pneumonia will be reassessed at the time of admission to the intensive care unit and 96 hours later.

Participants/Inclusion and exclusion criteria

Entry criteria: age between 18 to 65 years old; not having diseases such as cancer, diabetes and chronic obstructive pulmonary disease; not using drugs that weaken the immune system. No entry conditions: having more than 48 hours of mechanical ventilation before admission; requiring CPR.

Intervention groups

First intervention group: 48 patient will be rinsed with 2% chlorhexidine solution every 6 hours for 4 days by the researcher. The second intervention group: 48 patient will be rinsed every 6 hours for 4 days using SOD solution containing 2% vancomycin, 2% gentamicin and 2% colistin by the researcher. Control group: no intervention will be done by the researcher in patients (48 sample) and they will receive routine ward care (drug therapy, mouthwash if necessary).

Main outcome variables

Body temperature; lung infiltration; Pao₂/FIO₂; leukocyte count; culture of tracheal secretions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231007059641N1**

Registration date: **2023-12-28, 1402/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-28, 1402/10/07**

Update count: **0**

Registration date

2023-12-28, 1402/10/07

Registrant information

Name

IRAN Kamkary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5500 3140

Email address

mehdy5100221976@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the effect of selective oral decontamination regimen and chlorhexidine on rate of ventilator-associated pneumonia in patients admitted to the intensive care unit care of Beheshti hospital in Kashan 2023
Public title	The effect of selective oral decontamination regimen and chlorhexidine on rate of ventilator-associated pneumonia
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: Age between 18 to 65 years old Not having diseases such as cancer, diabetes and chronic obstructive pulmonary disease Not using drugs that weaken the immune system Exclusion criteria: Having more than 48 hours of mechanical ventilation before admission Requiring CPR
Age	From 18 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 96
Randomization (investigator's opinion)	Randomized
Randomization description	The samples will be determined by block randomization method with 10 blocks and using the random number table of Allocation Random software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research (Allocation Concealment). The sample allocation ratio (Allocation 1:1) will be in two groups of intervention and control (Assignment). Then, based on the obtained blocks and in the order of allocation, the intervention will be done. Blinding will not occur in this study.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Kashan University of Medical Sciences
Street address	School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran
City	Kashan
Province	Isfahan
Postal code	8715981151
Approval date	2023-09-10, 1402/06/19
Ethics committee reference number	IR.KAUMS.MEDNT.REC.1402.140
Health conditions studied	
<u>1</u>	
Description of health condition studied	Ventilator associated pneumonia
ICD-10 code	J18.9
ICD-10 code description	Pneumonia, unspecified
Primary outcomes	
<u>1</u>	
Description	Ventilator-associated pneumonia
Timepoint	At the time of admission and 96 hours after that
Method of measurement	To investigate pneumonia, the patient's body temperature using a mercury thermometer, the number of blood leukocytes using a venous blood test, pulmonary infiltration using chest X-ray, tracheal tube secretions using suction, Pao2 using ABG and fio2 using Pulse oximetry is measured.
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	First intervention group: Each patient will be rinsed with 2% chlorhexidine solution every 6 hours for 4 days by the researcher.
Category	Prevention

2

Description

The second intervention group: Each patient will be rinsed every 6 hours for 4 days using SOD solution containing 2% vancomycin, 2% gentamicin and 2% colistin by the researcher

Category

Prevention

3

Description

Control group: No intervention will be done by the researcher and they will receive routine ward care (drug therapy, mouthwash if necessary).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Mehdi kamkari

Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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Email

mehdy5100221976@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

Street address

Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mahdy Sabery

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

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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

Data of participants are confidential.

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

Not applicable

Data Dictionary

Not applicable