

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison the effect of open and closed endotracheal suction systems on the results of the smear and bacterial culture in patients under mechanical ventilation in intensive care unit

Protocol summary

Study aim

Comparison the effect of open and closed endotracheal suction systems on the results of the smear and bacterial culture in patients under mechanical ventilation

Design

A single-blind, randomized controlled clinical trial with parallel groups, with 52 patients (28 patients in open suction group and 28 patients in closed suction group) and evaluation of study outcomes after 72 h with smear and tracheal cultures in patients admitted to ICU ward of Valiasr Hospital in Birjand city

Settings and conduct

After final approval of the research topic by the Graduate Council and Regional Ethics Committee of Gonabad University of Medical Sciences and coordination with the research environment, informed consent was obtained from the caregiver and, if consent, at the beginning of the patient's admission to the ICU, a sample tracheal culture was obtained and sent to the central laboratory of Valiasr Hospital. Patients with negative primary cultures of endotracheal secretions were then selected and randomly assigned into two groups of open or closed suction and received the relevant intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have at least three days in the ICU, Being under mechanical ventilation, Lack of respiratory infections or sepsis, primary tracheal culture sample is negative, Not more than 6 hours after the patient's intubation, Accept ICU admission less than 24 hours after hospitalization; Exclusion criteria: Patient death, Use of immunosuppressive and antibiotic drugs use during the study period, Cardiopulmonary resuscitation, Extubation earlier than the expected

Intervention groups

Experimental group: receiving closed suction system;
Control group: receiving open suction system

Main outcome variables

The results of the smear and bacterial culture in patients under mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191014045110N1**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Fatemeh Rezaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

2019-04-04, 1398/01/15

Actual recruitment end date

2019-09-06, 1398/06/15 Trial completion date 2019-10-07, 1398/07/15 Scientific title Comparison the effect of open and closed endotracheal suction systems on the results of the smear and bacterial culture in patients under mechanical ventilation in intensive care unit Public title the effect of two methods endotracheal suction systems on the results of the smear and bacterial culture in patients under mechanical ventilation Purpose Prevention Inclusion/Exclusion criteria Inclusion criteria: Have at least three days stay in the ICU. Under mechanical ventilation (intubation or tracheostomy). Patient's primary endotracheal culture should be negative. Not more than 6 hours after the patient's intubation. Accept ICU admission less than 24 hours after hospital admission. Not have acute or chronic respiratory infections and sepsis. Exclusion criteria: Patient death Cardiopulmonary resuscitation Extubation earlier than expected Use of immunosuppressive drugs and start of antibiotic use during the study period Age From 20 years old to 80 years old Gender Both Phase N/A Groups that have been masked • Outcome assessor • Data analyser • Data and Safety Monitoring Board Sample size Target sample size: 56 Actual sample size reached: 52 Randomization (investigator's opinion) Randomized Randomization description Purpose-based sampling was performed among all patients admitted to the intensive care unit of Valiasr Hospital in Birjand, and if the inclusion criteria were met. In the second stage, patients were randomly assigned to either open or closed suction group. Patients whose right file number was even were assigned to the open suction group and patients with right file number was odd were assigned to the closed suction group. Blinding (investigator's opinion) Single blinded Blinding description Samples of endotracheal secretion culture sent to the laboratory were examined by a researcher who was one of experienced laboratory personnel and blind to division of study groups into open and closed suction groups. In addition, data analysis and outcome evaluation done by	someone other than the main researchers of the study. Placebo Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Regional Ethics Committee of Gonabad University of Medical Sciences Street address Gonabad university of Medical Sciences, Near Asian Road., Gonabad Town City Gonabad Province Razavi Khorasan Postal code 9691793718 Approval date 2019-01-29, 1397/11/09 Ethics committee reference number IR.GMU.1397.113 Health conditions studied 1 Description of health condition studied Patients under mechanical ventilation in intensive care unit ICD-10 code ICD-10 code description
	Primary outcomes 1 Description The results of the smear and bacterial culture in patients under mechanical ventilation Timepoint Before and 72 hours after intervention Method of measurement Microscope Secondary outcomes empty Intervention groups

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Description

Intervention group: In the closed suction system, without weaning from the ventilator and after the patient was hyperoxygenated with 100% oxygen by the ventilator and through the catheter that is placed between the endotracheal tube and ventilator Y-like device, suctioning was done. This procedure was done in various shifts by nurses who had received theoretical and practical training in the principles of suctioning.

Category

Prevention

2

Description

Control group: For suctioning in the open system group, after hyperoxygenated the patient with 100% oxygen for 1 minute by the ventilator and aseptic conditions (sterile gloves and sterile suction catheter) and removing the patient from the ventilator, suctioning was done. The suction catheter in this procedure was replaced after each use.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital affiliated with Birjand University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Gonabad 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

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Full name of responsible person

Fatemeh Rezaee

Position

Master Student in Critical Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Gonabad University of Medical Sciences

Full name of responsible person

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Latest degree

Master

Other areas of specialty/work