

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The Effects of Open and Closed Suction Methods on Occurrence of Ventilator Associated Pneumonia in patient who admitted in intensive care unit at sina hospital

Protocol summary

Study aim

comparing the open suctioning system versus closed suctioning system on occurrence of ventilator-dependent pneumonia in the ICU of Sinai hospital

Design

Randomized clinical trial with parallel control group, 40 patients enrolled between July 2019 and July 2020 with blinded outcome assessment using rand function in Microsoft Excel software

Settings and conduct

This project will be conducted in the intensive care unit at Sina hospital. Patients will be divided into two groups randomly. In the Open suction group, suction will be performed using a single-use catheter as the routine of the wards for a maximum of 15 seconds. In the closed suction group, suction will be performed and the suction catheter will be replaced every 48 hours. In both groups, prophylaxis standards against VAP will be followed. The following data will be collected for all patients: Gender, age, number of the days being under ventilator. VAP diagnosis will be made based on having CIPS criteria (CLINICALLY INFECTION PULMONARY SCORE) while being under mechanical ventilation for 48 hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are admitted to the intensive care unit at Sina hospital in 2019-2020; age>18 years; need of mechanical ventilation for at least 72 hours. Exclusion criteria: no satisfaction of patients family, patients who have pneumonia before the study

Intervention groups

Closed Suction: suction will be performed with closed system every one hour during ICU stay. open suction: suction will be performed by single-use routine catheters every one hour during ICU stay. The duration of suction will be less than 15 seconds.

Main outcome variables

Ventilator-associated pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100112003051N12**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Marzieh Khezri

Name of organization / entity

Qazvine University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1223 6376

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mkhezri@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-15, 1398/04/24

Expected recruitment end date

2020-07-14, 1399/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Open and Closed Suction Methods on Occurrence of Ventilator Associated Pneumonia in patient who admitted in intensive care unit at sina hospital

Public title

The Effects of Open and Closed Suction Methods on Occurrence of Ventilator Associated Pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient who are intubated for more than three days
Patients who are admitted in intensive care unit at Sina hospital

Exclusion criteria:

Patient who had pneumonia before study Patient who extubated in less than three days

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by using simple random allocation method (Random number table). Numbers extracted from tables that are odd are assigned to intervention group 1 and even numbers are assigned to control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Open and closed suction are performed by the nurse who not involved in the study, and the data is recorded by the researcher's colleague who is one personnel of ICU and, hence, the researcher is not aware of the recorded data.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical science

Street address

Tehran university of medical science, Poursina Ave.,16th Azar street.

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.414

Health conditions studied

1

Description of health condition studied

Ventilated associated pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

Incidence of ventilation associated pneumonia

Timepoint

Before intervention day1 day 2 day 3

Method of measurement

CIPS criteria (CLINICALLY INFECTION PULMONARY SCORE)The CPIS is calculated on the basis of points assigned for various signs and symptoms of pneumonia (eg, fever and extent of oxygenation impairment , tracheal suction and white blood cell count)

Secondary outcomes

1

Description

Pulse rate

Timepoint

Before and after suctioning

Method of measurement

Using non-invasive cardiac monitoring

2

Description

Respiratory rate

Timepoint

Before and after suctioning

Method of measurement

Using non invasive cardiac monitoring

3

Description

Arterial saturation of oxygen

Timepoint

Before and after suctioning

Method of measurement

Using pulse oximeter

4

Description

Temperature

Timepoint

Daily after suctioning

Method of measurement

Using tympanic thermometer

Intervention groups

1

Description

Intervention group (Closed Suction): suction will be performed with closed system every one hour during ICU stay.

Category

Treatment - Devices

2

Description

Control group(open suction): suction will be performed by single use routine catheters every one hour during ICU stay. Duration of suction will be less than 15 seconds.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Ali Atlasbaf

Street address

Sina hospital, Imam Khomeini Ave.

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

bami3h@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atabak Najafi

Street address

Sina Hospital, Imam Khomeini Ave.

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Email

bami3h@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ali Atlasbaf

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Atbak Najafi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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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

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

Yes - There is 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

Title and more details about the data/document

The data from the study will be published as an article.

When the data will become available and for how long

6 to 12 months

To whom data/document is available

Everyone in the field of medicine and nursing

Under which criteria data/document could be used

People who study the effects of suction type.

From where data/document is obtainable

Email to the person in charge of the project

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

Email to Applicant - Request from University Research Assistant - If the information is positive to Providing information to the applicant

Comments