

# 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

##### Email address

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.

##### City

Tehran

##### Province

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##### Postal code

1417653911

##### Phone

+98 21 8163 4208

##### 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

#### Street address

No. 5. Andishmand Ave., Mollasadra Blvd.

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**Postal code**  
5981134197  
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+98 28 3365 6495  
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bami3h@gmail.com

## 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**  
Anesthesiology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Latest degree**  
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**Other areas of specialty/work**

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Qazvin  
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**Email**  
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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