

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of open and closed suctioning methods on the incidence of premature ventilator-dependent pneumonia in mechanically ventilated patients

Protocol summary

Study aim

Comparison of open and closed suctioning methods on the incidence of premature ventilator-dependent pneumonia in mechanically ventilated patients

Design

This study was a clinical trial with a control group, with parallel groups, no blinding, randomized, on 184 patients that will be done by simple random method

Settings and conduct

Patients divided into two groups of intervention and control randomly, then in the intervention group close suction will be performed (in Amir Al-Momenin Hospital) and in the control group open suction will be performed (in Golestan Hospital)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Do not take drugs that weaken the immune system, No pneumonia before intervention according to the criteria of clinical instruments for measuring lung infection, At least 48 hours have elapsed since the patient was admitted, Breathing under mechanical ventilation Exclusion criteria: patient's unwillingness to cooperate

Intervention groups

Intervention group: In the intervention group, the close suction system will be used for 5 days. According to the order of the suction catheter manufacturer (Taiwanese company Biotech), the duration of use of this type of suction is 72 hours, which is disposable and can not be sterilized or reused. The suction set has two numbers 14 and 16. In this type of suction, suction is performed without the patient being separated from the ventilator. Control group: In the control group, the open suction system will be used for 5 days. In the control group, open suction, which is a routine method, is performed using green nelon with number 14 and orange with number 16, made by Iranian company Mehr Teb. In this type of suction, the patient is separated from the ventilator and

then suction is performed.

Main outcome variables

Incidence of ventilator-associated pneumonia, Rate of Endotracheal displacement and hypoxia changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201010048981N1**

Registration date: **2021-01-17, 1399/10/28**

Registration timing: **retrospective**

Last update: **2021-01-17, 1399/10/28**

Update count: **0**

Registration date

2021-01-17, 1399/10/28

Registrant information

Name

Zeinab Pakizeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8538

Email address

Zeinabpak74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of open and closed suctioning methods on the incidence of premature ventilator-dependent pneumonia in mechanically ventilated patients

Public title
Comparison of open and closed suction methods on the incidence of early ventilator-dependent pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Do not take drugs that weaken the immune system No pneumonia before intervention according to the criteria of clinical instruments for measuring lung infection At least 48 hours have elapsed since the patient was admitted. Breathing under mechanical ventilation
Exclusion criteria:
patient's unwillingness to cooperate

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **184**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of selecting patients will be simple random by Using a Random number table Which is prepared and adjusted by the consultant and according to it, even numbers will be assigned to the control group and odd numbers will be assigned to the intervention group, and nurses will be selected using convenience sampling method .

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology
Development of Ahvaz Jundishapur University of Medical Sciences and Health Services, University city, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2019-11-23, 1398/09/02
Ethics committee reference number
IR.AJUMS.REC.1399.229

Health conditions studied

1

Description of health condition studied
Patients admitted to the intensive care unit under a ventilator
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The rate of hypoxia changes
Timepoint
From the beginning of the study once a day to 5 days after the intervention
Method of measurement
Use of standard medical instrument checklist for clinical score of modified infection

2

Description
The Rate of Endotracheal displacement
Timepoint
From the beginning of the study once a day to 5 days after the intervention
Method of measurement
Use of standard medical instrument checklist for clinical score of modified infection

3

Description
Incidence of ventilator-associated pneumonia
Timepoint
From the beginning of the study once a day to 5 days after the intervention

Method of measurement

Use of standard medical instrument checklist for clinical score of modified infection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, closed suction method is used for 5 days. According to the order of the suction catheter manufacturer (Taiwanese company Biotech), the duration of use of this type of suction is 72 hours, which is disposable and can not be sterilized or reused. The suction set has two numbers 14 and 16. In this type of suction, suction is performed without the patient being separated from the ventilator.

Category

Prevention

2

Description

Control group: In the control group, open suction, which is a routine method, Performed for 5 days by using green nelaton with number 14 and orange with number 16, made by Iranian company Mehr Teb. Temporarily, the patient is disconnected from the ventilator and then the endotracheal tube suction is performed with a negative pressure of up to 120 mm Hg, once or twice, each time for 10 seconds.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Zeinab Pakizeh

Street address

Amir Al-Momenin Hospital, Shahid Rajaei St. (Sepidar), Ahwaz

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Web page address

2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Zeinab Pakizeh

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Golestan Educational and Medical Center, farvardin st, Golestan blv, Ahvaz

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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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

Ahwaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Zeinab Pakizeh
Position
Msc Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

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Zeinabpak74@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

No - There is not 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

Some of data such as main outcome information can be shared.

When the data will become available and for how long

Access period starts from 2021

To whom data/document is available

It will be available for people working in academic and scientific institutions

Under which criteria data/document could be used

After the article is published and the request is sent via email, part of the documentation will be available

From where data/document is obtainable

Sending Email to corresponding author of the article

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

Sending Email to corresponding author of the article

Comments