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 nelaton 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)

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+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 Ahwaz 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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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz 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
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Other areas of specialty/work
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Person responsible for updating data

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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
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