

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Nose and Mouth Disinfection with Chlorhexidine on indicators of respiratory infections in intubated patients with mechanical ventilation

Protocol summary

Summary

The purpose of this study is to determinate the effect of disinfection of "mouth and nose" compared with antiseptic "mouth alone" with chlorhexidine solution on indicators of respiratory infection in intubated patients under mechanical ventilation. Research design: A randomized, double-blind clinical trial. Inclusion Criteria: The patient has oral endotracheal tube and connected to ventilator; The patient does not have nasogastric tube; On arrival to the ICU respiratory infection symptoms was not seen. Exclusion criteria: The patient is less than 48 hours under mechanical ventilation; Symptoms of respiratory infection is observed in the first two days of mechanical ventilation. Sample size: 70 intubated patients under mechanical ventilation. Interventions: In the intervention group, antiseptic mouth and nose wash was done every 8 hours with 10 ml of 0.2% chlorhexidine preparation solution by the applicator for 30 seconds. in the control group, only oral antiseptic was used. Intervention time: For all patients, first intervention is performed in the first 12 hours connected to ventilator and this work continues until the end of the fifth day of mechanical ventilation. Primary outcomes: study of respiratory infection indicators based on clinical pulmonary infection score, including: amount of body temperature, amount and kind of Tracheal secretions, amount of Blood leukocytes, ratio of arterial Oxygenation, changes of chest radiographic and culture of tracheal secretions. Secondary outcomes: amount of Ventilator associated Pneumonia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051927969N1**
Registration date: **2016-07-09, 1395/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-09, 1395/04/19

Registrant information

Name

Mahdi Alimi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3841 2081

Email address

alimim1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Mashhad University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Nose and Mouth Disinfection with Chlorhexidine on indicators of respiratory infections in

intubated patients with mechanical ventilation

Public title

The Effect of Nose Disinfection with Chlorhexidine on Respiratory Infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: The satisfaction of patient's attendant to participate in the study; The patient's age is more than 18 years; The patient has endotracheal tube through the mouth; The patient has not nasogastric tube; Expecting mechanical ventilation for at least 48 hours; On arrival to the ICU lung infiltration on chest radiograph Does not exist; At least two of the three clinical criteria indicators of ventilator associated pneumonia (rectal temperature less than 35 or more than 38 degrees Celsius, leukocyte count of less than 4,000 or more than 12,000 per cubic millimeter of blood and purulent tracheal secretions) does not exist. Exclusion criteria: desire to continue participation in the study; Allergic reaction to chlorhexidine; Clear aspiration; At least two of the three clinical criteria indicators of ventilator associated pneumonia exist in the first or second day of mechanical ventilation

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Mashhad University of Medical Sciences

Street address

Qoreishi Building, Daneshgah St, Mashhad

City

Mashhad

Postal code

9177899191

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC.1394.493

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

Primary outcomes

1

Description

Amount of Body Temperature

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

By Glass Thermometer for Axillary in Degrees Celsius

2

Description

Amount of Tracheal secretions

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

Based on The Required Frequency of Tracheal Suctioning

3

Description

Kind of Tracheal secretions

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

On the basis of color, odor and secretions concentration and according to the nurse caring for the patient

4

Description

Amount of Blood leukocytes

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

By blood test

5

Description

Ratio of Arterial Oxygenation

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

By Analyze of Arterial Blood Gases

6

Description

changes of Chest radiographic

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

By the removable radiological devices (portable)

7

Description

Culture of tracheal secretions

Timepoint

up to Five Days after beginning of Intervention

Method of measurement

Quantitative culture with Gram stain

Secondary outcomes

1

Description

Ventilator associated Pneumonia

Timepoint

Up to five days after beginning of intervention

Method of measurement

By Clinical Pulmonary Infection Score

2

Description

The relationship between clinical criteria and diagnosis of pneumonia

Timepoint

Up to five days after beginning of intervention

Method of measurement

By Clinical Pulmonary Infection Score

Intervention groups

1

Description

In the intervention group, mouthwash (disinfection cheeks, gums, palate, tongue and teeth) every 8 hours with 10 ml of ready solution of 0.2% chlorhexidine is performed by the applicator for 30 second. Also every 8 hours after oral antiseptic, anti-infectious of nasal anterior openings is performed with 0.2% chlorhexidine solution by cotton swab. This continues until the end of the fifth day of mechanical ventilation.

Category

Prevention

2

Description

In the control group, mouthwash (disinfection cheeks, gums, palate, tongue and teeth) every 8 hours with 10 ml of ready solution of 0.2% chlorhexidine is performed by the applicator for 30 second. This continues until the end of the fifth day of mechanical ventilation. In this group is not done disinfection of nose.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital

Full name of responsible person

Street address

Shahid Kamyab Hospital, Fadaieyan Eslam Avenue, Nakhrisi Square, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeid Eslami

Street address

Ghoraishy Building, University St, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Alimi

Position

Nursing Expert, Nurse

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Person responsible for scientific inquiries

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Full name of responsible person

Zahra Sadat Manzari

Position

Nursing Ph.D, Assistant Professor

Other areas of specialty/work**Street address**

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Chaharah Doktora Crossing, Mashhad

City

Mashhad

Postal code**Phone**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty