

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of intermittent subglottic irrigation with NaCl %5 on the prevention of ventilator-associated pneumonia in critically ill patients

Protocol summary

Study aim

The effect of intermittent subglottic irrigation with NaCl %5 on the prevention of ventilator-associated pneumonia

Design

In this randomised, blinded clinical trial, 30 patients will be intubated by traction suction endo tracheal tube. Patients are randomly divided into two groups. In the intervention group subglottic area is washed by 10 CC of sodium chloride solution 5%. In the control group subglottic area is washed by 10 cc distilled water. Patients have been monitored for a maximum of two weeks. The incidence of ventilator-associated pneumonia is evaluated by the clinical pulmonary infection score.

Settings and conduct

This study will be conducted on patients underwent mechanical ventilation in intensive care units. The patients will be allocated to 1 of the 2 groups according to a randomization code list in a computer program. Patients and researchers are not aware of the treatment group.

Participants/Inclusion and exclusion criteria

Patients age between 20 to 50 years who have been under 24 hours of intubation.

Intervention groups

1. In the intervention group subglottic area is washed by 10 CC of sodium chloride solution 5%. 2. In the control group subglottic area is washed by 10 cc distilled water.

Main outcome variables

Patients will be monitored for a maximum of two weeks, and the incidence of ventilator-associated pneumonia is monitored by a clinical pulmonary infection score (CPIS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005363N10**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **retrospective**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

Registration date

2018-05-09, 1397/02/19

Registrant information

Name

Taraneh Naghibi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 2865

Email address

tnaghibi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-07-23, 1396/05/01

Trial completion date

empty

Scientific title

The effect of intermittent subglottic irrigation with NaCl %5 on the prevention of ventilator-associated pneumonia in critically ill patients

Public title

The effect of intermittent subglottic irrigation with NaCl %5 on the prevention of ventilator-associated pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients admitted to the ICU within 24 hours of intubation Patients age between 20 and 50 years Patient family satisfaction to participate in the research

Exclusion criteria:

Taking antibiotics jejunostomy or intravenous feeding Tracheostomy Pneumonia Patients without teeth

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be allocated to 1 of the 2 groups according to a randomization code list by a computer program.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients are not aware of the treatment group due to the decreased level of consciousness. The researcher who studies the variables, does not know the group of study and washing of subglottic is done by the nurse.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi square,Zanjan

City

Zanjan

Province

Zanjan

Postal code

4513994945

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.ZUMS.REC.1396.207

Health conditions studied**1****Description of health condition studied**

Ventilator Associated Pneumonia

ICD-10 code

J18

ICD-10 code description

Pneumonia, unspecified organism

Primary outcomes**1****Description**

pneumonia

Timepoint

Every three days

Method of measurement

Clinical Pulmonary Infection Score

Secondary outcomes**1****Description**

Connection to ventilator days

Timepoint

End of the study

Method of measurement

Records

2**Description**

length of ICU stay

Timepoint

End of the study

Method of measurement

Records

3**Description**

mortality during hospitalization in ICU

Timepoint

End of the study

Method of measurement

Records

Intervention groups

1

Description

Intervention group: All patients are intubated by an intubation tube with subglottic suction. In the intervention group subglottic area is washed by 10 ml of sodium chloride solution 5%.

Category

Prevention

2

Description

Control group: All patients are intubated by an intubation tube with subglottic suction. The control group subglottic area is washed by 10 ml distilled water.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mosavi Hospital

Full name of responsible person

Taraneh Naghibi

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Mosavi Hospital, Gavazang Road, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Ali Reza Shoghli

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Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi square, Zanjan

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Zahra Akbari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Naghibi

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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