Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 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 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
Street address
Mosavi Hospital, Gavazang Road, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4513994945
Phone
+98 24 3313 1559
Email
tnaghibi@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Ali Reza Shoghli
Street address
Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi square,Zanjan
City
Zanjan
Province
Zanjan
Postal code
4513994945
Phone
+98 24 3342 0677
Email
shoghli@zums.ac.ir
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
Street address
Mosavi Hospital, Gavazang Road, Zanjan, Iran
City
زنجان
Province
Zanjan
Postal code
4513994945
Phone
+98 24 3313 1559
Email
zkbari@zums.ac.ir

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
Anesthesiology

Street address
Mosavi Hospital, Gavazang Road, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4513994945
Phone
+98 24 3347 2865
Email
tnaghibi@zums.ac.ir

Person responsible for updating data

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
Anesthesiology
Street address
Mosavi Hospital, Gavazang Road, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4513994945
Phone
+98 24 3347 2865
Email
tnaghibi@zums.ac.ir

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