

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

##### 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

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**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**

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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