

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparison of mucoadhesive polymer gel containing chlorhexidine %0.2 and the solution of chlorhexidine%0.2 in the prevention of ventilator-associated pneumonia in patients who admitted in intensive care unit

#### Protocol summary

##### Summary

The aim of this study is to investigate the effect of mucoadhesive gel containing chlorhexidine in the prevention of ventilator-associated pneumonia in patients who admitted in the intensive care unit. This study is a clinical trial. 64 patients who connected to the ventilator that age between 20 and 50 years old will be enrolled in the study. If patients less than seven days to be extubated or to be discharged they will be excluded. Patients will be randomly divided into two groups. The first group will be received Mucoadhesive gel of chlorhexidine and the second group will be received chlorhexidine mouthwash. Every three days the incidence of ventilator-associated pneumonia will be assessed by Clinical Pulmonary Infection Score (CPIS) for 7 to 14 days. Finally, connection to ventilator days, length of intensive care unit stay and mortality rate will be compared between the two groups.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT201602095363N9**

Registration date: **2016-12-21, 1395/10/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-21, 1395/10/01

##### 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

Zanjan University of Medical Sciences

##### Expected recruitment start date

2016-03-19, 1394/12/29

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of mucoadhesive polymer gel containing chlorhexidine %0.2 and the solution of chlorhexidine%0.2 in the prevention of ventilator-associated pneumonia in patients who admitted in intensive care unit

##### Public title

The effect of mucoadhesive polymer gel containing chlorhexidine %0.2 in the prevention of ventilator-associated pneumonia

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Age between 20 and 50 years, Intubated patients and under mechanical ventilation, patients who have tooth, patients who are not pregnant,

patients who have not Tracheostomy or T tube, Do not feeding from jejunostomy, don't have parental feeding. exclusion criteria: Admission less than one week, Death in less than 7 days after intubation,Extubation in less than 7 days

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **64**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Table of random numbers will be used for Randomization in this study

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Zanjan University of Medical Sciences

##### Street address

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

##### City

Zanjan

##### Postal code

#### Approval date

2015-12-01, 1394/09/10

#### Ethics committee reference number

ZUMS.REC.1394.224

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator Associated Pneumonia

#### ICD-10 code

J69.8

#### ICD-10 code description

Pneumonitis due to other solids and liquids

## Primary outcomes

### 1

#### Description

Ventilator Associated Pneumonia

#### Timepoint

Third day, Sixth day, Ninth day, The twelfth day

#### 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 Intensive Care Unit stay

#### Timepoint

End of the study

#### Method of measurement

Records

### 3

#### Description

mortality during hospitalization in Intensive Care Unit

#### Timepoint

End of the study

#### Method of measurement

Records

## Intervention groups

### 1

#### Description

The first group 5 ml chlorhexidine 0.2% product of Behsa pharmaceutical company which will be produced to mucoadhesive form by the School of Pharmacy of Zanjan University of Medical Sciences as mouthwash will be received three times a day

#### Category

Treatment - Drugs

### 2

#### Description

The control group 5 ml oral solution containing chlorhexidine %0.2 product of Behsa pharmaceutical company as mouthwash will be received three times a day

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Mosavi Hospital

**Full name of responsible person**

Dr Taraneh Naghibi

**Street address**

Mosavi Hospital, Gavazang Road, Zanjan

**City**

Zanjan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice- Chancellor for Research of Zanjan University

**Full name of responsible person**

Vice- Chancellor for Research of Zanjan University of Medical Sciences, Shoghli MD, PhD

**Street address**

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

**City**

Zanjan

**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 of Zanjan University

**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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Ali Zargar

**Position**

Medical Student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Taraneh Naghibi

**Position**

ICU Fellowship, Assistant Professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Dr Taraneh Naghibi

**Position**

ICU Fellowship, Assistant Professor

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## 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*