

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparing prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes in Prevention of ventilator-associated pneumonia on intubated patients in ICU

#### Protocol summary

##### Summary

Objectives)To compare prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes on preventing ventilator-associated pneumonia in intubated patients admitted in ICU. Design) A prospective randomized clinical trial. Participants and settings) Ninety six internal or surgical patients with age range of 18-65 years that have intubated in ICU for first time will randomly allocated in three groups. Patients with intubation before admission in ICU, prior history of immune compromised conditions or pneumonia will exclude from study. Intervention) Intubation will be by polyurethane-Cylindric cuffed endotracheal tubes in group A, polyurethane tapered cuffed in group B and Polyvinyl chloride cuffed in group C. Outcome) All patients will follow for development of ventilator associated pneumonia (VAP).

#### General information

##### Acronym

VAP

##### IRCT registration information

IRCT registration number: **IRCT201112163915N4**

Registration date: **2011-12-21, 1390/09/30**

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

Last update:

Update count: **0**

##### Registration date

2011-12-21, 1390/09/30

##### Registrant information

###### Name

Manizheh Mostafa Gharehbaghi

###### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1526 2253

##### Email address

peirovifara@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2011-06-22, 1390/04/01

##### Expected recruitment end date

2012-03-20, 1391/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes in Prevention of ventilator-associated pneumonia on intubated patients in ICU

##### Public title

Comparing prophylactic effects of polyurethane-Cylindric and Tapered cuffed and Polyvinyl chloride cuffed endotracheal tubes in Prevention of ventilator-associated pneumonia on intubated patients in ICU

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: intubation in ICU for first time; age range 18-65 years; internal medicine or surgical cases.

exclusion criteria: intubation prior to ICU admission;  
history of immune compromised conditions; pneumonia.

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **96**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of Tabriz University of Medical  
Sciences

##### Street address

Tabriz University of Medical Sciences, Gholghasht  
Street

##### City

Tabriz

##### Postal code

#### Approval date

2011-08-07, 1390/05/16

#### Ethics committee reference number

5/4/3862

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator Associated Pneumonia

#### ICD-10 code

J95.8

#### ICD-10 code description

Other postprocedural respiratory disorders

## Primary outcomes

### 1

#### Description

Ventilator associated pneumonia

#### Timepoint

During hospitalization in ICU

#### Method of measurement

Chest x-ray (progressive infiltration and consolidation)  
with two items of body temperature below 36.5 or above  
38.5, leukocyte count less than 1500 or more than  
10000, purulent tracheal aspirate, positive culture  
aspirate

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

group A : intubation with polyurethane-Cylindric cuffed  
endotracheal tubes,

#### Category

Treatment - Devices

### 2

#### Description

group B: Intubation with polyurethane-Tapered cuffed  
endotracheal tubes,

#### Category

Treatment - Devices

### 3

#### Description

group C: intubation with Polyvinyl chloride cuffed  
endotracheal tubes

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohada Hospital

##### Full name of responsible person

Ali Peirovifar

##### Street address

Operation room, Emam Reza Hospital, Gholghasht  
street

##### City

Tabriz

## Sponsors / Funding sources

# 1

## Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Rashidi

**Street address**

Tabriz university of Medical Sciences, Ghoghashst Street

**City**

Tabriz

**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, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Peirovifar

**Position**

Associate Professor of Anesthesiology

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## Person responsible for updating data

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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*