

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of EVAC tracheal tube in reducing ventilator associated pneumonia in critically patients of intensive care unit

Protocol summary

Summary

Almost 10-28% of ICU patients suffer from Ventilator Associated Pneumonia (VAP) which increases mortality two times and increases length of stay in hospital and cost. As macro or microaspiration of gastric or oropharynx secretions to lower airway due to bacterial colonization of aerodigestive tract is one of the risk factors for VAP, a device that aspirates these secretions can help us. EVAC is a newly designed endotracheal tube which has a dorsal lumen above the cuff for suction of subglottic secretions. As there is not enough evidence about the effect of EVAC tube on reducing VAP, we decided to evaluate the effect of EVAC tube on reducing VAP compared to routine tubes in critically ill patients. After approval of the study in ethics committee of Tabriz Medical University, 90 patients aging more than 18 year-old which will be intubated more than 72 hours will be entered in this study. Patients will randomly allocated to two 45-patient groups: EVAC group and Standard group. All standard and routine care will be done in patients and all patients will be monitored for VAP and will receive the therapeutic options. Age, sex, APACHE score, Pao₂/Fio₂, Duration of mechanical ventilation, tracheostomy, reintubation, cuff pressure, number of tube cuff suctioning per day and mortality will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012272582N3**
Registration date: **2011-01-10, 1389/10/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-10, 1389/10/20

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-01-10, 1389/10/20

Expected recruitment end date

2012-01-10, 1390/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of EVAC tracheal tube in reducing ventilator associated pneumonia in critically patients of intensive care unit

Public title

The effect of endotracheal tube on pneumonia in ICU patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ICU patients with age more than 18 y. old who will be intubated for more than 72 hours.

Exclusion criteria: Previous history of HIV, pregnancy,

mechanical ventilation, malignancy, immunosuppression or leucopenia with leukocyte count less than 1000/mm3.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Tabriz Medical University

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2012-01-10, 1390/10/20

Ethics committee reference number

5/4/7376

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J09, J10,

ICD-10 code description

Influenza and pneumonia

Primary outcomes

1

Description

ventilatory associated pneumonia

Timepoint

During ICU stay

Method of measurement

CIPS (Clinically infectious pulmonary score)

Secondary outcomes

1

Description

Length of ICU stay

Timepoint

During ICU stay

Method of measurement

days of ICU stay

2

Description

mortality

Timepoint

During ICU stay

Method of measurement

being alive or death

Intervention groups

1

Description

Intervention group: patient will be intubated with EVAC endotracheal tubes

Category

Other

2

Description

Control group: patients will be intubated with routine endotracheal tubes

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

General ICU of Shohada hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

El-goli street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of medical sciences

Full name of responsible person

Alireza Ostad Rahimi

Street address

Faculty of Health and Nutrition

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

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Web page address

Person responsible for updating data

Contact

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