Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Ventilatory Associated Pnuemonia (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 commitee 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
Ata Mahmoodpoor
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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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 intubted for more than 72 hours.
Exclusion criteria: Previous history of HIV, pregnancy,

mechanical ventilation, malignancy, immunosuppresion 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 (Clinicaly 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 routin endotracheasl 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

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Position
Assistant Professor,PhD of Nutrition

Other areas of specialty/work

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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