Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Early tracheostomy versus Late tracheostomy, comparison of morbidity and mortality in Shariati Hospital's ICU between 2014 and 2015

Protocol summary

Summary

Background: This randomized clinical trial is designed to determine the optimum timing for tracheostomy in intensive care unit patients (intubated and ventilator dependent) and to compare benefits, complications and mortality between early and late tracheostomy. Materials & Methods: Inclusion criteria: Intensive care unit cases, Intubated and ventilator dependent and patient anticipated to be ventilator dependent for more than 7 days (According to clinical conditions and by physician's opinion). Exclusion criteria: Emergency tracheostomy, Tracheostomy performed between 10th and 13rd days and Tracheostomy after 28th day. Eligible 162 patients admitted in Shariati Hospital between 2014 and 2015 were randomly categorized in two groups (early and late tracheostomy). Sequential Organ Failure Assessment (SOFA) score was used to compare the severity of illness before tracheostomy. Open tracheostomy was performed only by a single surgeon. Complications, mortality, as well as ICU and total hospital stay were compared between two groups. Key words: early Tracheostomy, late tracheostomy, infection, hospital stay

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011025934N1**
Registration date: **2016-04-28, 1395/02/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-28, 1395/02/09

Registrant information

Name

Amir Fazlali

Name of organization / entity

Shariati hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 4085

Email address

dr.fazlali@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early tracheostomy versus Late tracheostomy, comparison of morbidity and mortality in Shariati Hospital's ICU between 2014 and 2015

Public title

Define the best time for tracheotomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Admission in Surgical and Medical ICU; Intubated an dependent to ventilator; Need more than 7 days of intubation based on physician judgment
Exclusion criteria: Emergent tracheostomy; Combination of tracheotomy and another operation; Tracheostomy between days of 10 to 13; Tracheostomy after the day

28
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **162**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Tehran University of Medical Sciences
Street address
Medical School Building, Poursina st., 16 Azar st., Enqelab sq., Tehran
City
Tehran
Postal code
Approval date
2016-01-30, 1394/11/10
Ethics committee reference number
IR.TUMS.REC.1394.1779

Health conditions studied

1

Description of health condition studied
Tracheostomy time managment
ICD-10 code
Z93.0
ICD-10 code description
Tracheostomy status

Primary outcomes

1

Description
Arythmia
Timepoint
Post Op to Extubation
Method of measurement
Cardiac Monitoring and then EKG

2

Description
Infectious complication
Timepoint
Post Op to Extubation
Method of measurement
Bacterimia, Fungemia, Sepsis and Septic shok

3

Description
Respiratory complication
Timepoint
Post Op to Extubation
Method of measurement
Atelectasia, Pneumonia and ARDS (CXR and CT Scan)

4

Description
MOD
Timepoint
Post Op to Extubation
Method of measurement
Renal, Hepatic, Coagulation and ....

5

Description
Mortality
Timepoint
Post Op to Extubation
Method of measurement
Viatla sign

6

Description
Intubation and ICU stay time
Timepoint
Post Op to Extubation
Method of measurement
Documentation

Secondary outcomes

empty

Intervention groups

1

Description
Control: Open tracheotomy (a small incision below the

cricoid cartilage, thyroid isthmectomy and then tracheotomy) was performed in the operating room under general anesthesia for patients

Category

Treatment - Surgery

2

Description

InterventionI: Open tracheotomy (a small incision below the cricoid cartilage, thyroid isthmectomy and then tracheotomy) was performed in the operating room under general anesthesia for patients

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr. Amir Fazlali

Street address

General surgery ward - Shatiati hospital - Jalal-e al-e Ahmad cross - North Kargar st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Kaviani

Street address

Poor sina st., 16th Azar st., Enqelab sq., Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Shariati hospital

Full name of responsible person

Amir Fazlali

Position

General surgery resident

Other areas of specialty/work

Street address

General surgeryward - Shatiati hospital - Jalal-e al-e ahmad cross - north Kargar st.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shatiati hospital

Full name of responsible person

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Position

Thorax surgen

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shariati hospital

Full name of responsible person

Amir Fazlali

Position

General surgery resident

Other areas of specialty/work

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City

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Web page address

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