

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 management

#### 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**

Intervention!: 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.

**City**

Tehran

**Postal code****Phone**

+98 21849012455

**Fax****Email**

dr.fazlali@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shatiati hospital

**Full name of responsible person**

Dr. Ali Ghorbani Abdegah

**Position**

Thorax surgen

**Other areas of specialty/work****Street address**

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

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aliabdehgah@yahoo.com

**Web page address****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****Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21849012455

**Fax**

**Email**

dr.fazlali@gmail.com

**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*