

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Success and Complications in Mini-surgical and Standard Methods in ICU patients at Masih Daneshvari Hospital

#### Protocol summary

##### Summary

In this study, morbidity and mortality were compared for two methods mini-surgical tracheostomy and standard percutaneous dilational tracheostomy. In this study, 320 patients were enrolled, 160 patients were treated by mini-surgical tracheostomy and 160 patients by standard percutaneous dilatational tracheostomy. These methods were performed on ICU bed. In mini-surgical method unlike standard percutaneous dilational tracheostomy, two layers are separated from each other along one vertical and one horizontal incision, and then dissection. Throughout all stages of the procedure full monitoring of Electrocardiography, pulse oximetry and blood pressure were done. Primary outcome was amount of bleeding and length of stay in intensive care unit also were compared in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015040120592N3**  
Registration date: **2015-04-20, 1394/01/31**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-04-20, 1394/01/31

##### Registrant information

##### Name

Seyed Mohammad Reza Hashemian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2610 9944

##### Email address

iran.criticalcare@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

None

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Success and Complications in Mini-surgical and Standard Methods in ICU patients at Masih Daneshvari Hospital

##### Public title

The effect of surgery type on bleeding in hospitalized patients in intensive care unit

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Guardian consent; age between 17 through 75; Placed under mechanical ventilation for at least 7 days from the Endotracheal Tube and require mechanical ventilation exclusion criteria: Patients with unstable cervical vertebrae; Interstate and severe disease in the study intervention; Severe coagulopathy; Surgical wound infection

##### Age

From **17 years** old to **75 years** old

##### Gender

Both

## Phase

3

### Groups that have been masked

No information

### Sample size

Target sample size: 320

### 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

Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences,  
Velenjak, Shahid Chamran Highway, Tehran, Iran

##### City

Tehran

##### Postal code

##### Approval date

2012-09-22, 1391/07/01

##### Ethics committee reference number

None

## Health conditions studied

### 1

#### Description of health condition studied

Mechanical Ventilator

#### ICD-10 code

Z51.8

#### ICD-10 code description

Other specified medical care

## Primary outcomes

### 1

#### Description

Bleeding

#### Timepoint

Start of study

#### Method of measurement

Observation

## Secondary outcomes

### 1

#### Description

Time of Surgery

#### Timepoint

Start of Study

#### Method of measurement

Observation

### 2

#### Description

Decrease of O2saturation

#### Timepoint

Start of Study

#### Method of measurement

Observation

## Intervention groups

### 1

#### Description

Intervention group (Mini-surgical method): All anticoagulants stopped at least 12 hours before the procedure or after indicated correction of coagulopathy. Patient lied supinely on the bed. following prepping and draping the cricoid is palpated and a 2-cm vertical skin incision made 1 cm below the cricoid cartilage. Attending physician stood at the head of the bed and the assistant fellow stood at the right side of patient. Our modified PDT technique, msPDT, utilized a Tracoe® experec dilatation set.

#### Category

Treatment - Surgery

### 2

#### Description

control group: All STs were performed in the operative suite using standard techniques described elsewhere.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Seyed Mohammad Reza Hashemian

##### Street address

Masih Daneshvari Hospital, Dara'abad Street,  
Niavaran Street, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Mehdi Sadoghi

**Street address**

Shahid Beheshti University of Medical Sciences,  
Velenjak, Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Masih Daneshvari Hospital

**Full name of responsible person**

Seyed Mohammad Reza Hashemian

**Position**

Associate Professor

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

Masih Daneshvari Hospital, Darabad, Shahid Bahonar  
Street, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 912 111 9279

**Fax****Email**

iran.criticalcare@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Seyed Mohammad Reza Hashemian

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## Person responsible for updating data

**Contact****Name of organization / entity**

Masih Daneshvari Hospital

**Full name of responsible person**

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**Position**

Associate Professor

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Masih Daneshvari Hospital, Dara'abad Street,  
Niavaran Street, Tehran, Iran

**City**

Tehran

**Postal code****Phone****Fax****Email**

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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*