

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® expc 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

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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**

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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