Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison between early tracheostomy and orotracheal intubation in critically ill COVID-19 patients.

Protocol summary

Study aim
The outcome assessment of the early tracheotomy and orotracheal intubation in COVID-19 patients.
Design
Two arm parallel group without blinding and randomization
Settings and conduct
The study conducted on the total confirmed COVID-19 patients using the Polymerase Chain Reaction (PCR) technique and radiologic studies that admitted in the ICU centers of a tertiary hospital during one month. All patients required invasive ventilation. The patients categorized into two groups according to methods of airway management and divided randomly into the groups. Data analyzed using statistical package for social sciences (SPSS) version 18 (SPSS Inc. Chicago, IL, USA) for windows.
Participants/Inclusion and exclusion criteria
All patients required invasive ventilation.
Intervention groups
The early tracheotomy is conduction of tracheotomy surgery within at least 3 days from orotracheal intubation. The orotracheal intubation is the insertion of an endotracheal tube through the mouth and into the trachea.
Main outcome variables
Mortality rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180129038542N1**
Registration date: **2020-04-13, 1399/01/25**
Registration timing: **retrospective**

Last update: **2020-04-13, 1399/01/25**
Update count: **0**
Registration date
2020-04-13, 1399/01/25

Registrant information
Name
Shahriar Najafizadeh-Sari
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-06, 1399/01/18
Expected recruitment end date
2020-04-12, 1399/01/24
Actual recruitment start date
2020-04-06, 1399/01/18
Actual recruitment end date
2020-04-12, 1399/01/24
Trial completion date
2020-04-13, 1399/01/25

Scientific title
The comparison between early tracheostomy and orotracheal intubation in critically ill COVID-19 patients.

Public title
Early tracheostomy in COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The critically ill patients who were required mechanical ventilation

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The other similar studies are about the patients who required mechanical ventilation with many different conditions such as severe head trauma, acute respiratory distress syndrome, traumatic patients, etc. This is the first study about early tracheostomy and intubation in critically ill patients with COVID-19.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences

Street address
No.5, West Mollasadra st., Vanak Sq., Baqiyatallah Hospital, Department of Surgery

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Tehran

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1655889874

Approval date
2020-04-05, 1399/01/17

Ethics committee reference number
IR.BMSU.REC.1399.055

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
The oxygen blood saturation

Timepoint
Every 12 hours from the first day of hospitalization to the last day

Method of measurement
The pulse oximetry

2

Description
Respiratory rate

Timepoint
0-1-2-3-4-7-14 days after starting intervention

Method of measurement
Counting the number of breaths per minute

3

Description
The mortality rate

Timepoint
10, 20 days after starting intervention

Method of measurement
Counting deaths

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group received medications for the treatment of COVID-19 based on the Fifth Edition of the Novel Corona Virus Guidelines, in addition they indicated for mechanical ventilation and the airway management was selected using the tracheotomy tube within 3 days from intubation.

Category
Treatment - Surgery

2

Description
Control group: Patients in this group received medications for the treatment of COVID-19 based on the Fifth Edition of the Novel Corona Virus Guidelines, in addition they indicated for mechanical ventilation and the airway management was selected using the Orotracheal tube.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Early Tracheotomy in COVID-19
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Shahriar Najafizadeh
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
After the completion of the study, the information on the main outcome will be shared.

When the data will become available and for how long
6 months after printing

To whom data/document is available
All researchers can take action.

Under which criteria data/document could be used
Data and results will be available to all researchers for research on COVID-19.

From where data/document is obtainable
Dr.najafi73@yahoo.com

What processes are involved for a request to access data/document
The data will be provided to the applicant after a review and approval of the request within a month.

Comments