Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of using Covid۱۹ intubation box on success rate and time of tracheal intubation in patients undergoing surgery under general anesthesia

Protocol summary

Study aim
Effect of using Covid۱۹ intubation box on success rate and time of tracheal intubation in patients undergoing surgery under general anesthesia

Design
This study is a double-blind clinical trial with parallel, randomized, phase 3 groups per 100 patients. Block randomization method is used for randomization

Settings and conduct
After obtaining informed consent, patients are randomly selected into two groups. In both groups, preoperative clinical examinations are performed. For patients, complete monitoring is performed and fluid therapy is performed, then anesthesia drugs are injected in both groups to initiate anesthesia and airway intubation is given as follows: midazolam 0.02 mg by weight, fentanyl 3 micrograms by weight , propofol 2 mg by weight and atracurium 0.5 mg by weight. Then airway intubation is performed in both groups and the time of entry of the endotracheal tube into the mouth to enter the glottis is recorded and measured. Success in intubation is also recorded in both groups. Covid box intubation consists of a simple transparent cubic chamber that has two inlets for the hands of the anesthesiologist to enter the airway intubation.This study is performed in Firoozgar Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient with ASA1,2 , Patient with Malampati scale1,2 Patients aged between 20 and 60 years

Intervention groups
Intervention group: patients candidate for surgery under general anesthesia with airway intubation using Covid۱۹ intubation box Control group: patients candidate for surgery under general anesthesia with normal airway intubation

Main outcome variables
Airway intubation time, success rate of airway intubation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140109016151N10**
Registration date: **2021-11-27, 1400/09/06**
Registration timing: **prospective**

Last update: **2021-11-27, 1400/09/06**
Update count: **0**

Registration date
2021-11-27, 1400/09/06

Registrant information

Name
Alireza Pournajafian

Name of organization / entity
Iran University of Medical Siences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-21, 1400/09/30

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using Covid۱۹ intubation box on success rate and time of tracheal intubation in patients undergoing surgery under general anesthesia

Public title

Effect of using Covid۱۹ intubation box on success rate and time of tracheal intubation in patients undergoing surgery under general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with ASA 1 , 2 Patient with Malampati scale 1 , 2 Patients aged between 20 and 60 years

Exclusion criteria:

Failure to airway intubation after two attempts with Covid۱۹ intubation box Defective airway intubation tools

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method. to randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

8874113911

Approval date

2021-03-02, 1399/12/12

Ethics committee reference number

IR.IUMS.FMD.REC.1399.780

Health conditions studied

1

Description of health condition studied

General surgery

ICD-10 code

Y81.1

ICD-10 code description

Therapeutic (nonsurgical) and rehabilitative general- and plastic-surgery devices associated with adverse incidents

Primary outcomes

1

Description

Airway intubation time

Timepoint

Beginning of induction of anesthesia

Method of measurement

The watch

Secondary outcomes

1

Description

Success rate of airway intubation

Timepoint

Beginning of induction of anesthesia

Method of measurement

Observation

Intervention groups

1

Description
Intervention group: Intervention group: After obtaining informed consent, patients are randomly selected into two groups. In the first group, preoperative clinical examinations are performed. For patients, complete monitoring is performed and fluid therapy is performed, then anesthesia drugs to initiate anesthesia and airway intubation are injected as follows: midazolam 0.02 mg by weight, fentanyl 3 micrograms by weight, propofol 2 Mg by weight and atracurium 0.5 mg by weight.Then, for the patients in the intervention group, Covid 19 Box intubation consists of a clear, cubic-shaped clear acrylic chamber with two inlets for the anesthesiologist to insert into the airway. airway intubation is then performed and the time it takes for the endotracheal tube to enter the mouth to enter the glottis is recorded and measured. Success in airway intubation is also recorded.

Category
Treatment - Devices

2

Description
Control group: Control group: After obtaining informed consent, patients are randomly selected into two groups. In the control group, preoperative clinical examinations are performed. For patients, complete monitoring is performed and fluid therapy is performed, then anesthesia drugs to initiate anesthesia and airway intubation are injected as follows: midazolam 0.02 mg by weight, fentanyl 3 micrograms by weight, propofol 2 Mg by weight and atracurium 0.5 mg by weight. Then, for the patients in the control group, airway intubation is performed normally using a laryngoscope and Macintosh blade No. 4. Then airway intubation is performed and the time of endotracheal tube entry into the mouth to enter the glottis is recorded and measured. Be. Success rates for airway intubation are also recorded.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Alireza Pournajafian
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Sponsors / Funding sources

1

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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
Iran University of Medical Sciences
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
Iran University of Medical Sciences
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Position
Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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