Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of high-pressure nasal cannula and conventional oxygen treatment in Covid-19 patients referred to the emergency department

Protocol summary

Study aim
Comparison of the effect of high-pressure oxygen treatment and traditional oxygen in Covid 19 patients referred to the emergency department

Design
Double-blind, randomized parallel-group clinical trial

Settings and conduct
After obtaining the code of ethics from the ethics committee of Isfahan University of Medical Sciences, Covid-19 patients who have been admitted to the emergency department and are eligible for the study are treated with nasal oxygen for at least 15 minutes and then if they do not improve and do not increase the oxygen saturation above 90% to continue the treatment of patients are divided into two groups. In the study group, high-pressure nasal oxygen is used for patients, and in the control group, an oxygen mask with oxygen greater than or equal to 6 liters per minute is used. Patients must be treated for at least one hour before admission and then evaluated. Outcomes are compared between the two groups of patients. Vital signs including heart rate, respiration rate, systolic and diastolic blood pressure, and arterial blood gas parameters will be evaluated at the beginning of treatment and one hour after treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Conscious and adult patients with oxygen saturation less than 90% despite receiving nasal oxygen or respiratory rate more than 24 breaths per minute in whom the diagnosis of Covid-19 is confirmed by PCR or lung HRCT. Exclusion criteria: Unstable hemodynamics and the need for emergency intubation, respiratory failure due to cardiopulmonary edema and pregnant women

Intervention groups
In the study group, high-pressure nasal oxygen is used for patients, and in the control group, a non-rebreather oxygen mask with oxygen greater than or equal to 6 liters per minute is used.

Main outcome variables
Intubation rate; ICU admission rate; duration of ICU and hospital stay; mortality rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180129038549N15**
Registration date: **2021-12-20, 1400/09/29**
Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**
Update count: **0**

Registration date
2021-12-20, 1400/09/29

Registrant information

Name
Farhad Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
drfarhadheydari@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of high-pressure nasal cannula and conventional oxygen treatment in Covid-19 patients referred to the emergency department

Public title
Effect of high-pressure nasal cannula and conventional oxygen treatment in Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Oxygen saturation less than 90% despite receiving nasal oxygen ≥ 3 L/min or respiratory rate more than 24 breaths per minute The diagnosis of Covid-19 is confirmed based on PCR or lung HRCT Alert patients
Exclusion criteria:
Unstable hemodynamics Obesity Hypoventilation Syndrome Respiratory failure due to pulmonary edema Patients who do not tolerate the use of high pressure oxygen Cases in which emergency intubation is required Pregnant women
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
After the arrival of the patients to the emergency department, they are divided into 2 groups by a computer-generated random number table with 4 blocks. The selected subjects will be divided into each study group in a randomized block method using 9 rows of four blocks (ABAB-BABA-ABBA-BAAB-AABB-BBAA). Case group (A) and control group (B). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are first treated with nasal oxygen for at least 15 minutes and then if they do not improve and do not increase the oxygen saturation above 90% to continue treatment of patients are divided into two groups. In the study group, high-pressure nasal oxygen is used for patients, and in the control group, an oxygen mask with oxygen greater than or equal to 6 liters per minute is used. Patients must be treated for at least one hour before entering the study and then evaluated. Then all the information is collected by a researcher who is blinded to randomization.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-11-26, 1400/09/05
Ethics committee reference number
IR.MUI.MED.REC.1400.657

Health conditions studied

1

Description of health condition studied
Respiratory failure
ICD-10 code
J96.0
ICD-10 code description
Acute respiratory failure

2

Description of health condition studied
Covid-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Increased blood oxygen saturation
Timepoint
One hour after treatment
Method of measurement
Pulse oximetry

Secondary outcomes

1

Description
Vital signs include heart rate and respiratory rate and systolic and diastolic blood pressure
Timepoint
One hour after treatment
Method of measurement
Manometer(pressure gauge) and count

2

Description
Intubation rate
Timepoint
Until discharge from the hospital
Method of measurement
Count

3

Description
Intensive care unit admission rate
Timepoint
Until discharge from the hospital
Method of measurement
Count

4

Description
Mortality rate
Timepoint
Until discharge from the hospital
Method of measurement
Count

Intervention groups

1

Description
Intervention group: Covid-19 patients admitted to the emergency department are first treated with nasal oxygen for at least 15 minutes and then, if they do not improve and the oxygen level in the pulse oximetry does not exceed 90%, continue treatment with high-pressure nasal cannula up to a maximum of 60 liters per minute. Patients must be treated for at least one hour before entering the study and then evaluated.
Category
Treatment - Drugs

2

Description
Control group: Covid-19 patients admitted to the emergency department are initially treated with normal nasal oxygen for at least 15 minutes. If there is no improvement and no increase in oxygen level in the pulse oximetry above 90%, to continue treatment for patients, a non-rebreather oxygen mask with oxygen greater than or equal to 6 liters per minute for one hour is used and then patients are evaluated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Farhad Heydari
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Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Farhad Heydari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All of the data after coding
When the data will become available and for how long
Six months after publication
To whom data/document is available

Everyone

Under which criteria data/document could be used

For seemingly studies data released to academic chairman's

From where data/document is obtainable

Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Emailing to farhad_heidari@med.mui.ac.ir

Comments