

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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)

Phone

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Email address

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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 \geq 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

Isfahan

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