Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of oxygen delivery through high flow nasal cannula (HFNC) with different temperatures in improving the clinical symptoms of COVID-19 patients

Protocol summary

Study aim

Evaluation of the effect of using high flow oxygen delivery through a nasal cannula (HFNC) with different temperatures in COVID-19 patients referred to Masih Daneshvari Hospital

Design

The present study is a clinical trial with three intervention groups, with parallel and one-way blind groups, randomized, and with a sample size of 30 patients.

Settings and conduct

This study is a clinical trial in patients with COVID-19 referred to Masih Daneshvari Hospital in Tehran who have moderate to severe disease and need to be hospitalized and receive respiratory support. Clinical conditions and laboratory tests and analysis of blood gases of patients before and after receiving high flow oxygen through the nasal cannula will be examined. Randomization is done using codes assigned to each patient and using the file number. The primary caregiver is aware of how the groups are assigned. Other blind groups include the researcher analyzing the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Evidence of new coronavirus, Saturation˂90, Signature of written consent form Participation in the study, age over 18 years, and patients with moderate or severe COVID-19 in need of hospitalization and respiratory support. Exclusion criteria: Pregnancy and Breastfeeding, decreased patient level of consciousness

Intervention groups

Patients with COVID-19 who are require respiratory support are divided into three groups. In the first group, high-flow oxygen delivery through the nasal cannula (HFNC) is regulated at 31 ° C, in the second group at 34 ° C and in the third group at 37 ° C. Also, the flow of oxygen to the patient is the same in all three groups and is 40 liters per minute.

Main outcome variables

Oxygen saturation, ferritin, interleukin 6, c-reactive protein, Erythrocyte sedimentation rate, alanine aminotransferase, aspartate aminotransferase, D-dimer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047727N4**
Registration date: **2021-04-28, 1400/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-28, 1400/02/08**
Update count: **0**

Registration date

2021-04-28, 1400/02/08

Registrant information

Name

Maryam Sadat Mirenayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 5050

Email address

mirenayat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-06-20, 1400/03/30

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

Scientific title
The effectiveness of oxygen delivery through high flow nasal cannula (HFNC) with different temperatures in improving the clinical symptoms of COVID-19 patients

Public title
Evaluation of the effect of high flow oxygen delivery under different temperatures in COVID-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New coronavirus detection (clinical or paraclinical) Oxygen saturation less than 90% Written consent to participate in the study Age over 18 years Moderate to severe Covid-19 disease is hospitalized and requires respiratory support
Exclusion criteria:
PaCO2>65 PH<7.28 Cardiovascular disorders that prevent pulmonary rehabilitation
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
With simple randomization and using random number table and individual randomization unit. For randomization, we use a table consisting of random digits 1 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each figure is assigned to a treatment group. We start from the first row of the table and move from row to row. For the three treatments, we put the numbers 1 to 3 for treatment A, the numbers 4 to 6 for treatment B, and the numbers 7 to 9 for treatment C. We will continue the above process until the two groups are completed.
Blinding (investigator's opinion)
Single blinded
Blinding description
To prevent any possible complications, the doctor and clinical caregiver are fully aware of the specificity of the treatment groups. Patients in the study were also not blinded to the type of treatment they were receiving. Researchers responsible for data collection and analysis are not aware of the allocation of different study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Dr. Masih Daneshvari Hospital, Darabad, Shahid Bahonar St. (Niavaran)
City
Tehran
Province
Tehran
Postal code
1956944413
Approval date
2021-03-08, 1399/12/18
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.221

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.01
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Oxygen saturation
Timepoint
Before starting oxygen therapy, 24 hours later
Method of measurement
Pulse oxymetry

2

Description
Partial pressure of carbon dioxide
Timepoint
Before starting oxygen therapy, 24 hours later, 7 days later
Method of measurement

VBG analysis

3

Description
Interleukin 6
Timepoint
Before starting oxygen therapy, 24 hours later, 7 days later
Method of measurement
Laboratory tests

4

Description
C-Reactive Protein
Timepoint
Before starting oxygen therapy, 24 hours later, 7 days later
Method of measurement
Laboratory tests

5

Description
Erythrocyte Sedimentation Rate
Timepoint
Before starting oxygen therapy, 24 hours later, 7 days later
Method of measurement
Laboratory tests

6

Description
Ferritin
Timepoint
Before starting oxygen therapy, 24 hours later, 7 days later
Method of measurement
Laboratory tests

Secondary outcomes

1

Description
Borg scale
Timepoint
Before starting oxygen therapy, every day for a week
Method of measurement
Borg questionnaire

Intervention groups

1

Description
First intervention group: In this group, patients undergo oxygen therapy with a high-flow device for "24 hours". This device transmits hot and humid air with high flow (up to 60 l / min) through the nasal cannula to patients. Temperature and flow are adjustable. In this group of patients, the temperature of the air transferred to the patient is set at 31 ° C.
Category
Treatment - Devices

2

Description
Second intervention group: In this group, patients undergo oxygen therapy with a high-flow device for "24 hours". This device transmits hot and humid air with high flow (up to 60 l / min) through the nasal cannula to patients. Temperature and flow are adjustable. In this group of patients, the temperature of the air transferred to the patient is set at 34 ° C.
Category
Treatment - Devices

3

Description
Third intervention group: In this group, patients undergo oxygen therapy with a high-flow device for "24 hours". This device transmits hot and humid air with high flow (up to 60 l / min) through the nasal cannula to patients. Temperature and flow are adjustable. In this group of patients, the temperature of the air transferred to the patient is set at 37 ° C.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Narjes Jalali
Street address
Masih Daneshvari Hospital, Darabd
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 5050
Email
narjesjalali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Dr. Afshin Zarghi

Street address
Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2243 9781

Email
Mpajouhesh@sbmu.ac.ir

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
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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maryam Sadat Mirenayat

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Masih Daneshvari Hospital, Darabad

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
mirenayat_m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maryam Sadat Mirenayat

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Masih Daneshvari Hospital, Darabad

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
mirenayat_m@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Reyhaneh Zahiri

Position
Researcher

Latest degree
Master

Other areas of specialty/work
Biothechnology

Street address
Masih Daneshvari Hospital, Darabad

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
zahirireyhane@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available