

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of efficacy and safety of morphine through nebulizer mask in the treatment of acute respiratory distress due to Covid-19 in adult patients

Protocol summary

Study aim

Evaluation of efficacy and safety of morphine through nebulizer mask in the treatment of acute respiratory distress caused by Covid-19 in adult patients

Design

In this randomized double-blind clinical trial study, patients were randomly divided into two groups of 30 based on a random number table: Morphine with nebulizer mask and Control: Normal saline with nebulizer mask.

Settings and conduct

Patients with acute respiratory distress due to Covid-19 referred to Shahid Madani Hospital in Karaj will be randomly divided into two groups of 30 randomly in one of the intervention / control groups.

Participants/Inclusion and exclusion criteria

This study will be performed in patients with acute respiratory distress due to Covid-19 referred to Shahid Madani Hospital in Karaj in 1400, and Patients with high suspicion / diagnosis of heart failure and unstable angina, severe shock with hemodynamic instability despite increased vascular pressure, severe / undiagnosed pulmonary infection for other reasons (COPD, lung fibrosis, lung cancer, pneumonia Bacterial ...), diagnosis of pulmonary hemorrhage, pregnancy / lactation, other important cause besides ARDS for respiratory failure, need for ECMO during the study, is expected to be transferred to another hospital within 72 hours, known allergies to Morphine, allergy or contraindication to exogenous and endogenous opioids, obesity (BMI > 35 kg / m²) will not be included in the study.

Intervention groups

Intervention group: Patients receive morphine with nebulizer mask immediately after admission to the ward or emergency department + standard treatments based on hospital guideline. Control group: Patients with normal

saline nebulizer mask immediately after admission to the ward or emergency department + standard treatments based on hospital guidelines.

Main outcome variables

Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211112053042N2**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

Mohammad Hossein Delshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3350 2347

Email address

m.delshad@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-20, 1400/09/29

Expected recruitment end date

2022-03-15, 1400/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of morphine through nebulizer mask in the treatment of acute respiratory distress due to Covid-19 in adult patients

Public title

The effect of morphine with nebulizer mask in the treatment of acute respiratory distress in adult patients with Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 80-18 years Patients with a definitive diagnosis of Covid-19 based on PCR test within 48 hours after hospitalization Acute moderate respiratory distress syndrome with PaO₂ / FiO₂ <200 based on Berlin criteria (Force et al., 2012) Patients with severe dyspnea Patients in the end-stages of the disease Lack of proper treatment Patients with consent to participate in the project

Exclusion criteria:

Patients with high suspicion / diagnosis of heart failure and unstable angina Existence of severe shock with hemodynamic instability despite increased vascular pressure Severe / undiagnosed lung infection for other reasons (chronic obstructive pulmonary disease, pulmonary fibrosis, lung cancer, bacterial pneumonia ...) Diagnosis of pulmonary hemorrhage Pregnancy / breastfeeding An important cause other than acute respiratory distress for respiratory failure Requires ECMO during the study period He/she is expected to be transferred to another hospital within 72 hours Known allergies to morphine Sensitivity or contraindication to exogenous and endogenous opioids Obesity (BMI>35 kg/m²) Patients with dissatisfaction with participating in the project

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are divided into two groups based on a table of random numbers. Random number table is a set of

numbers that are produced without a specific pattern or order and in a completely random manner and become a table. In order to use a random number table, the researcher must first predetermine the table to read the numbers (for example, up, down, left, or right). Individual for the control group). The researcher then touches one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients (intervention or control) will receive encoded sealed envelopes. The coding will be done by one of the project partners and the doctor, the evaluator and the patient will be blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

Street address

second floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2021-10-16, 1400/07/24

Ethics committee reference number

IR.ABZUMS.REC.1400.217

Health conditions studied**1****Description of health condition studied**

Acute respiratory distress caused by Covid-19

ICD-10 code

B97.2

ICD-10 code description

Coronavirus as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Mortality rate

Timepoint

During hospitalization

Method of measurement

Based on the patient's record

Secondary outcomes

1

Description

oxygen saturation level

Timepoint

Morphine dose before titration, 2 hours after first titration, 2 hours after second titration, 2 hours after third titration, 2 hours after effective drug titration, 12 hours after effective drug titration, 24 hours after effective drug titration

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Intervention group: Patients receive morphine with a nebulizer mask immediately after admission to the ward or emergency room.

Category

Treatment - Drugs

2

Description

Control group: Patients receive normal saline with a nebulizer mask immediately after admission to the ward or emergency room.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani Hospital

Full name of responsible person

Mohammad Hossein Delshad MD.

Street address

Shahid Madani Square, Jahanshahr, Karaj

City

Karaj

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Alborz

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31437 44693

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m.delshad@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Hatam Godini P.H.D

Street address

Saffarian alley, 45 meters from Golshahr, Karaj

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Email

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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

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Hossein Delshad MD.

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Arghavan Gharbi, 45 meters from Golshahr Street,

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Person responsible for scientific inquiries

Contact

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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

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

Research centers and faculty members

Under which criteria data/document could be used

At the request of the researcher and faculty members

From where data/document is obtainable

Send email to the scientific respondent

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

Within two months from the time of requesting and sending the email, the documents will be sent to the mentioned people

Comments