

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of dexmedetomidine in sedation of COVID-19 critically ill patients hospitalized in the intensive care unit , A double blind clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of dexmedetomidine in sedation of COVID-19 critically ill patients hospitalized in the intensive care unit.

Design

A single blind, randomized clinical trial with parallel groups design of 60 patients

Settings and conduct

In this study patients, using the block randomization method with a ratio of 1: 1 will be randomly entered into either of the two control or intervention groups. Sixty critically ill patients of Covid-19 will be divided into two groups of 30. The intervention group will be named A and the control group will be named B. This study is single blind. Participants and therapists in charge of the treatment will be aware and radiologists, researchers evaluating the research and statistics will be blind about the patients group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 75 years, with respiratory and breathing distress, Oxygen saturation less than 93% or positive polymerase chain reaction test, admitted to the Intensive Care unit, connected to non-invasive or invasive ventilation, requiring sedative administration. Exclusion criteria: Pregnancy, known allergic to opioids or dexmedetomidine.

Intervention groups

Control group will receive standard Covid-19 drug therapy including remdesivir, interferon, and corticosteroids, and supplements in addition to the standard sedation regimen including a fentanyl and morphine pump that based on the patient's need will be at a rate of 3 Up to 5 ml per hour. The intervention group, who will receive the standard Covid-19 treatment regimen along with dexmedetomidine for sedation. The dose of dexmedetomidine is 0.2-1.5 micrograms per kilogram per hour, which can vary depending on the

patient's condition.

Main outcome variables

possible side effects of the drug, patient oxygen saturation percentage, Agitation and delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110425006280N13**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Mohammad Haghighi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3211 1319

Email address

mohaghighi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of dexmedetomidine in sedation of COVID-19 critically ill patients hospitalized in the intensive care unit , A double blind clinical trial

Public title

Evaluation of the effectiveness of dexmedetomidineine sedation of COVID-19 critically ill patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 75 years admitted to the Intensive Care unit clinical diagnosis of respiratory distress and breathing distress Oxygen saturation less than 93% or positive polymerase chain reaction test connected to non-invasive or invasive ventilation requiring sedative administration.

Exclusion criteria:

Pregnant patients Known allergies to opioid drugs or dexmedomeidine.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be randomly assigned to each of the two groups (control or intervention) using block randomization with a ratio of 1:1. 60 of the critically ill COVID-19 patients will be divided into two groups of 30. Intervention and control groups will be called A and the control group will be named B. Random blocking will be assigned to research units in numbers 1-30, respectively. Then a table with 6 rows called blocks and each block will have 4 parts and each part will be named with A and B, will be considered. In the next step, the numbers are placed in each house in order. After all the numbers are placed in the blocks, the people who had the number in house A will receive the intervention medicine and the people who had the number in house B will be considered as the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Each patient's group therapy will be determined only

after randomization. Participants and physicians responsible for caring for patients' health will not be blinded and will be informed of the treatment group. Radiologists, researchers evaluating research and statisticians will be blind to the treatment group of patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of Guilan University of Medical Sciences

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

City

Rasht

Province

Guilan

Postal code

4193713189

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.GUMS.REC.1400.156

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

The effect of dexmedomedine in COVID-19 patients.

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Clinical Symptoms of COVID-19

Timepoint

The total time of the study will be done within 15 days at 8-hour intervals.

Method of measurement

questionnaire form

Secondary outcomes

1

Description

Relaxation of critically ill patients with 19 ICUs in terms of agitation and delirium

Timepoint

The duration of examination of patients in the ICU is 15 days. This scoring is done for patients at intervals of 8 hours and the average will be evaluated.

Method of measurement

During the period of hospitalization, they will be examined for vital signs and intubation. Delirium and agitation will be assessed based on the Richmond Restlessness-Drowsiness Scale (RSAA). This scale is defined in the scoring range between 0-1. According to this scale, agitation includes items: +1 restless, +2 agitated, 3+ very agitated, +4 fighter. In the case of delirium, it is divided into 0 alert and calm, -1 drowsiness, -2 mild sedation, -3 moderate sedation, -4 deep anesthesia, and -5 absence of any awakening.

Intervention groups

1

Description

Intervention group consists of 30 patients, which will receive the standard regimen of COVID-19 treatment including ramdisvir, interferon and corticosteroids and supplements in addition to dexmedetomidine for sedation. Dexmedetomidine is produced by Elixir Pharmaceutical Company, which is in form of a 200 Micrograms in a 2 millilitres vial. The total time of this study will be 15 days. Evaluation of clinical status of patients will be on 8-hour intervals, based on questionnaire form and variables of the study.

Category

Treatment - Drugs

2

Description

Control group: consists of 30 patients, who will receive standard treatment of COVID-19 mentioned as above plus standard sedative treatment regimen which is a fentanyl and morphine pump, including a vial of fentanyl and a vial of morphine and will be injected at a speed of 3-5 millilitre per hour based on the patients need for relaxation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Mohammad Haghighi

Street address

Razi Hospital, Sardar Jangal Street, Rasht

City

Rasht

Province

Guilan

Postal code

41448 95655

Phone

+98 13 3355 0028

Fax

Email

razi.hospital@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Guilan university of medical sciences

Full name of responsible person

Dr Mohammadreza Naghipoor

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

City

Rasht

Province

Guilan

Postal code

6694941446

Phone

+98 13 3333 5821

Email

naghi@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice President of Research Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Full professor of Critical Care Medicine

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Razi Hospital, Sardar Jangal Street, Rasht

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 1322 3970

Email

manesthesist@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Professor of Critical Care Medicine

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Razi Hospital, Sardar Jangal Street, Rasht

City

rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 1322 3970

Fax

+98 13 1323 9842

Email

manesthesist@gmail.com

Web page address

https://isid.research.ac.ir/Mohammad_Haghighi2

Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohadese Ahmadi

Position

Research Expert/(MSc) English

Latest degree

Master

Other areas of specialty/work

Expert of Research Affairs

Street address

Anesthesiology Reseach Center, Alzahra Hospital,
Namjoo Street

City

Rasht

Province

Guilan

Postal code

4144654839

Phone

+98 13 3336 9328

Email

p.ahmadi2311@gmail.com

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