Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 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 dexmedomedine.

Intervention groups
Control group will recieve standard Covid-19 drug therapy including remedicivir, 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

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Iran (Islamic Republic of)

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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
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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 recieve the standard regimen of COVID-19 treatment including ramdisvir, interferen and corticosteroids and supplements in addition to dexmedtomidine for sedation. Dexmedtomidine 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
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Position
Full professor of Critical Care Medicine
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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