# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**Country**
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**
Vice President of Research Guilan university of medical sciences

**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
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**Position**
Full professor of Critical Care Medicine
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## Person responsible for updating data

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**Other areas of specialty/work**
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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