

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy and safety of Clonidine vs Alprazolam in reducing anxiety of Covid-19 patients in the Intensive Care Unit

Protocol summary

Study aim

evaluation of the efficacy and safety of Clonidine and Alprazolam consumption in COVID-19 ICU admitted patients

Design

phase 3 double blinded randomized clinical trial study. Randomization performed by RAND function in MS office excel. It contains two parallel intervention groups each groups 50 persons.

Settings and conduct

This study will be performed in the 501 AJA hospital ICU ward in Iran on COVID-19 conscious patients. Participants randomly divided into two groups. a group will receive 0.1mg Clonidine orally BD another group will receive 0.5 mg Alprazolam daily.

Participants/Inclusion and exclusion criteria

COVID-19 conscious ICU admitted patients will enter the study. Patients with unstable hemodynamics or loss of consciousness will not enter the study.

Intervention groups

there are two groups in our study, a group will receive 0.1mg Clonidine orally BD another group will receive 0.5 mg Alprazolam daily. Patients will be evaluate daily for the anxiety level with NRS scale. Also. adverse events such as Bradycardia, Hypotension and delirium will be registered if happen.

Main outcome variables

change in the anxiety state according to NRS scale; Hypotension occurrence; Bradycardia occurrence; Delirium occurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211015052773N1**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

Registration date

2021-11-05, 1400/08/14

Registrant information

Name

Mohammad Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-05, 1400/08/14

Expected recruitment end date

2021-12-17, 1400/09/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of Clonidine vs Alprazolam in reducing anxiety of Covid-19 patients in the Intensive Care Unit

Public title

Efficacy and safety of Clonidine vs Alprazolam in sedating covid-19 ICU patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COVID -19 disease with positive PCR test ICU admission consciousness

Exclusion criteria:
unconsciousness and GCS reduction heart rate below 50 bps DPB below 60mmhg SBP below 90mmhg second degree AV block and over Delirium during admission

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into clonidine and alprazolam receiving groups with simple random method by using the random number table. The random number function was used to randomize and assign individuals to groups; Randomization using Excel software is as follows: First, in a column, the groups are entered as A, B and below each other; because the number of samples in each group is set to 35 (taking into account the sample loss), 35 A and 35 B must be entered in order and below each other. In the opposite column, random numbers are generated using the RAND command. In the next step, with using the sort command, random numbers are generated from small to large or vice versa, which causes the order of the groups A and B to be changed. In fact, using the new order, individuals are randomly assigned to the case and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double blinded study means that patients are not aware of the exact drugs that is being prescribed for them and they just know that in this study they are going to receive Alprazolam or Clonidine. drug boxes' will not be shown to the patients even we will use similar drug shapes and the shape of the tablets of Clonidine and Alprazolam are same to patients can not recognize the exact type of drugs. one of the researchers will prescribe Alprazolam or Clonidine according to random number table results. another researchers will collect the clinical results without knowing which drugs has been prescribed for each patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA university of medical sciences

Street address

5th unit-no25- Safavian alley, Tehranvilla St, Sattarkhan St.

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Tehran

Province

Tehran

Postal code

1444783846

Approval date

2021-09-26, 1400/07/04

Ethics committee reference number

IR.AJAUMS.REC.1400.157

Health conditions studied

1

Description of health condition studied

anxiety in ICU admitted COVID-19 patients

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

anxiety level score in numeral verbal rating scale

Timepoint

daily from the date of admission until clearance or death

Method of measurement

anxiety numeral verbal rating scale

2

Description

hypotension

Timepoint

each 6 hours from the date of admission until clearance or death

Method of measurement

mercury manometer

3

Description

bradycardia

Timepoint

each 6 hours from the date of admitting until clearance or death

Method of measurement

radial pulse checking

4**Description**

Delirium

Timepoint

daily from the date of admission until death or clearance

Method of measurement

Diagnostic and Statistical Manual of Mental Disorders guideline, 5th Edition

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 0.5 mg Alprazolam tablet (Abidi company) start from the date of admission until death or clearance

Category

Treatment - Drugs

2**Description**

Intervention group: 0.1 mg Clonidine tablet (Tolidaroo Company) start from the date of admission until death or clearance

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza (501) hospital of AJA

Full name of responsible person

Dr. Ebrahim Hazrati

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh 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

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Mohammad Bagheri

Position

Reasercher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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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