

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 NVRS 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 NVRS 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)

###### Phone

+98 21 6650 2417

###### Email address

mohammadbagheri777@sbmu.ac.ir

##### 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.

**City**

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 addition 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

**Street address**

Imam Reza (501) hospital of AJA, Etemadzadeh St, Fatemi St

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

Artesh University of Medical Sciences

**Full name of responsible person**

Mojtaba Yousefi Zashk

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Dr.hazrati.e@gmail.com

**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**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Name of organization / entity**

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**Position**

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**Latest degree**

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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