Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
hypotention

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
City
Tehran
Province
Tehran
Postal code
14117118541
Phone
+98 21 8609 6350
Email
Dr.hazrati.e@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mojtaba Yousefi Zashk
Street address
AJA University of Medical Sciences, Etemadzadeh Avenue, West Fatemi Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14117118541
Phone
+98 21 8609 6350
Email
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
Street address
5th unit- no25- Safavian alley, Tehranvilla St. Sattarkhan St
City
Tehran
Province
Tehran
Postal code

1444783846

Phone
+98 21 6650 2417

Email
mohammadbagheri@lotusmedco.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Mohammad Bagheri

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
No 25, Safavian alley, Tehranvilla St. Sattarkhan St

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Province
Tehran

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Phone
+98 21 6650 2417

Fax

Email
mohammadbagheri777@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Mohammad Bagheri

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Postal code
1444783846

Phone
+98 21 6650 2417

Fax

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mohammadbagheri777@sbmu.ac.ir

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