Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the effect of ketamine and midazolam with morphine on the rate of depressive and anxiety disorders and PTSD in mechanically ventilated patients in the intensive care unit

Protocol summary

Study aim
Determining the effect of ketamine on the rate of depressive, anxiety and PTSD disorders after discharge from ICU

Design
Clinical trial with control group, block randomization, Fourty seven patients in each group with parallel groups, double blinded.

Settings and conduct
The study population is patients admitted to the ICU of 5 Azar Hospital in 1399. A total of 94 people were selected as available and assigned to the two groups receiving ketamine and midazolam with morphine using four-block random allocation. Patients after ICU discharge if the Glasgow Coma Scale (GCS) is greater than or equal to 14 are included in the study and HADS and PTSD questionnaires are administered by telephone at two weeks, two months later and six months later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients should be mechanically ventilated in the ICU for at least 48 hours، Measurement Acute Physiology and Chronic Health Evaluation II Upon entering the ICU، Age range 18-60 years؛ Exclusion criteria: Patients due to drug poisoning، Patients due to suicide، Patients after، cardiopulmonary resuscitation Post CPR، Patients with a history of brain dementia and Alzheimer's، Patients with extensive cerebral hemorrhage، Patients with GCS = 3 at the time of admission to the ICU، Patients with a history of taking neurological drugs

Intervention groups
Intervention group: The ketamine group is infused at a dose of 0.5 mg / kg for 15 minutes, followed by an intravenous infusion of 0.5 µ/kg/h. Control group: Midazolam at 3-5mg / h and morphine at 2-3mg / h.

Main outcome variables
The rate of depressive disorders, anxiety and PTSD.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170413033408N5**
Registration date: **2021-02-07, 1399/11/19**
Registration timing: **prospective**

Last update: **2021-02-07, 1399/11/19**
Update count: **0**

Registration date
2021-02-07, 1399/11/19

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 17 3254 9891
Email address
dr.mojaveraghili@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of ketamine and midazolam with morphine on the rate of depressive and anxiety disorders and PTSD in mechanically ventilated patients in the intensive care unit

Public title
Determining the effect of ketamine on the rate of depressive, anxiety and PTSD disorders after discharge from ICU

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients should be mechanically ventilated in the ICU for at least 48 hours. Measurement Acute Physiology and Chronic Health Evaluation II Upon entering the ICU Age range 18-60 years

Exclusion criteria:
Patients due to drug poisoning Patients due to suicide Patients after cardiopulmonary resuscitation Post CPR Patients with a history of brain dementia and Alzheimer's Patients with extensive cerebral hemorrhage Patients with GCS = 3 at the time of admission to the ICU Patients with a history of taking neurological drugs

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be assigned to the groups receiving ketamine and midazolam in a four-block.Therefore, we will have 6 blocks in which the order of allocating samples in groups is (AABB-ABAB-ABBA-BAAB-BABA-BBAA) and each of the blocks is assigned numbers from 1 to 6 and randomly from 1 to 6 Select a number and select the block corresponding to the desired number and assign the patients to the two groups according to the block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Assignment of samples to groups is done by a specialist physician so that it is not possible for the physician to blind. Patients are unaware that they are assigned to the ketamine and midazolam groups. In addition, the psychiatrist will be unaware of how patients are assigned to the groups during data collection during the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences

Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Golestan, Iran

City
Gorgan

Province
Golestan

Postal code
49341-74515

Approval date
2020-11-15, 1399/08/25

Ethics committee reference number
IR.GOUMS.REC.1399.318

Health conditions studied

1

Description of health condition studied
depressive and anxiety disorders

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

2

Description of health condition studied
Post traumatic stress disorder

ICD-10 code
F43.1

ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
The rate of depressive disorders

Timepoint
Mean score of depressive disorders during two weeks, two months and six months after discharge.

Method of measurement
The first interview was conducted two weeks later and

the next interview was conducted two months later and six months later by telephone using Beck Depression questionnaire.

2

Description
Anxiety Disorders
Timepoint
Mean score of anxiety disorders during two weeks, two months and six months after discharge.
Method of measurement
The first interview was conducted two weeks later and the next interview was conducted two months later and six months later by telephone using the Beck Anxiety questionnaire.

3

Description
PTSD Disorders
Timepoint
Mean score of PTSD disorders during two weeks, two months and six months after discharge.
Method of measurement
The first interview was conducted two weeks later and the next interview two months later and six months later by telephone using the PCI questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The ketamine group is infused at a dose of 0.5 mg / kg for 15 minutes, followed by an intravenous infusion of 0.5 µ/kg/h.
Category
Treatment - Drugs

2

Description
Control group: Midazolam at 3-5mg / h and morphine at 2-3mg / h.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan 5 Azar Educational and Medical Center
Full name of responsible person
Dr.Babak mojaver aghili
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Gorgan-Sari road 4th kilometers, Golestan University of Medical Sciences, School of Medicine - Anesthesiology Department
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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
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
dr Babak Mojaver Aghilli
Position
Anesthesiologist, Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the main outcome
When the data will become available and for how long
Since 2021
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
No manipulation, mentioning the data reference
From where data/document is obtainable
Seyed Babak Mojaver Aghili, drbabaka35@gmail.com, Golestan University of Medical Sciences, Deputy of Research and Technology, Gorgan, Golestan, Iran, Gorgan, 4 km, Sari,
What processes are involved for a request to access data/document
sending an email, complete the personal and professional characteristics with documentation
Comments