

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

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Province

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan 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

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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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**Person responsible for updating data****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person