

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the efficacy of ketamine-midazolam combination with midazolam alone in the treatment of status epilepticus resistant to first- and second-line treatments in patients with refractory status epilepticus

Protocol summary

Study aim

Comparison of the effect of ketamine combined with midazolam compared to midazolam alone in reducing complications and mortality, reducing recurrence and shortening the duration of seizures in patients with treatment-resistant status seizures.

Design

The study is a feasibility study and a pilot, and due to the small size of the sample, it will not be done randomly, and it will have two groups of ten people.

Settings and conduct

The study will be conducted at Namazi Hospital in the intensive care unit on patients with status epilepticus who are resistant to first and second line treatment. One study group will be given midazolam alone and the other group will be given midazolam and ketamine. And complications and mortality rates are measured.

Participants/Inclusion and exclusion criteria

Eighteen to fifty-year-old patients with refractory status epilepticus are included in the study, and pregnant people; patients with multi organ failure; patients with high blood pressure or evidence of increased intracranial pressure are excluded from the study.

Intervention groups

For one group, simultaneous treatment with ketamine and midazolam and in the other group, treatment with midazolam alone is used. For the group receiving ketamine, it is important to pay attention to the patient's blood pressure, the absence of high intracerebral pressure and no evidence of acute myocardial ischemia. For the control group, which received midazolam alone. It is important to note that the patient's blood pressure is not low.

Main outcome variables

shortening the duration of a long sustained seizure; reducing the recurrence of seizures; Examination of complications of prolonged seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221022056269N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

fateme kiani ara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4263

Email address

fateme81kiani71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-24, 1401/09/03

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of ketamine-midazolam combination with midazolam alone in the treatment of status epilepticus resistant to first- and second-line treatments in patients with refractory status epilepticus

Public title

effect of midazolam- ketamine combination in refractory status epilepticus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with refractory status epilepticus Age between 18-50 years old

Exclusion criteria:

The pregnant patients The patients with sepsis Post hypoxic patients The patients with multi organ damage The patients with high blood pressure and increased intracranial pressure

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of medicine- Shiraz university of medical Sciences.

Street address

Namazi Square of Namazi Hospital

City

Shiraz

Province

Fars

Postal code

71936-13311

Approval date

2022-10-02, 1401/07/10

Ethics committee reference number

IR.SUMS.MED.REC.1401.349

Health conditions studied

1

Description of health condition studied

Refractory status epilepticus

ICD-10 code

G96.8

ICD-10 code description

Other disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

Level of consciousness, galasco coma score

Timepoint

The beginning of the study and one hour later and twenty four hours later.

Method of measurement

glasco score coma

2

Description

status seizure termination time

Timepoint

one hour later

Method of measurement

Based on the patient's clinical symptoms

Secondary outcomes

1

Description

The secondary outcome variable is the examination of the amount of drug side effects in the two study groups, which is checked based on the patient's clinical symptoms.

Timepoint

At the beginning of the study, the blood pressure and heart rate of the patients and the electrocardiogram of the patients are taken.

Method of measurement

Use of sphygmomanometer and heart rate monitor.

Intervention groups

1

Description

Intervention group: The intervention group of ketamine drug, which is part of the category of anesthetic drugs, in

the form of intravenous injection with a dose of 3 mg along with midazolam with a bolus dose of .2 Mg/kg and maintenance dose: starting with .1 Mg per kilogram of body weight is injected in one minute up to a maximum dose of 2 mg per kilogram of body weight per minute, which is continued for twenty-four hours in case of clinical response.

Category

Treatment - Drugs

2**Description**

Control group: the group receiving midazolam alone with a bolus dose of .2 Mg/kg and maintenance dose: starting with .1miligrams per kilogram of body weight are injected in one minute up to a maximum dose of 2 Mg per kilogram of body weight per minute, which is continued for twenty-four hours in case of clinical response.

Category

Treatment - Drugs

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

Namazi hospital

Full name of responsible person

Fateme Kiani ara

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

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Full name of responsible person

Mohammad hashem Hashempoor

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The central building of Shiraz University of Medical Sciences, Zand Street in front of Palestine Street

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Kiani ara

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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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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Person responsible for updating data

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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