

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative effect of Lorazepam with Midazolam in sedative of patients under mechanical ventilatin hospitalized in Intensive care unit of Imam Khomeyni Hospital

#### Protocol summary

##### Study aim

Determining the comparison of sedative effect of lorazepam with midazolam in mechanically ventilated patients admitted to the intensive care unit of Imam Khomeini Hospital in Urmia

##### Design

Clinical trial with parallel, double-blind, randomized, phase 3 on 110 patients. Excel software rand function is used for randomization.

##### Settings and conduct

During the study, intubated patients will be randomly divided into two groups using M midazolam and L lorazepam using computer and will receive one of the two drugs intravenous midazolam or intravenous lorazepam. During the study, demographic information (age and sex, BMI, vital signs (blood pressure, heart rate, respiration rate, oxygen saturation)), level of consciousness (GCS), Richmond standard score and Ramsay scale score of patients in terms of relaxation level and other items Variables will be recorded in a checklist prepared by the researcher. Side effects of the two drugs are rare, the most serious side effect of these drugs is respiratory arrest, in which case the antidote of these drugs (flumazenil) will be used for injection. The patient and the intern do not know the type of drug received for sedation. In this study, no cost will be borne by the patient.

##### Participants/Inclusion and exclusion criteria

In this study, patients enter the study based on the age of 18-65 and the level of consciousness and recent lack of benzodiazepines, and if the above cases are excluded from the study.

##### Intervention groups

Patients under mechanical ventilation admitted to the intensive care unit

##### Main outcome variables

Age, gender, Richmond benchmark score, cryptographic

scoring system, Glasgow index, body mass index, cause of intubation, cause of hospitalization, type of drug, cost of drug used, side effects, duration of mechanical ventilation, mortality rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220424054631N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

##### Registration date

2022-05-14, 1401/02/24

##### Registrant information

##### Name

Amin Nourollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 4434 0023

##### Email address

amin1816@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-30, 1401/02/10

##### Expected recruitment end date

2022-08-01, 1401/05/10

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparative effect of Lorazepam with Midazolam in sedative of patients under mechanical ventilatin hospitalized in Intensive care unit of Imam Khomeyni Hospital

**Public title**  
Comparative effect of Lorazepam with Midazolam in sedative of patients under mechanical ventilatin hospitalized

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Pulmonary patients under mechanical ventilation with appropriate level of consciousness (equivalent to GCS $\geq$ 10) Age 18-65 years Patients who have not received benzodiazepines in the last 72 hours

**Exclusion criteria:**  
Patients with inadequate level of consciousness GCS <10  
Patients with unstable hemodynamics Allergy to benzodiazepines or contraindications to the use of benzodiazepines Age under 18 or over 65 years Patients with neurological disorders, kidney or liver failure  
Patients who have recently received or are dependent on long-acting benzodiazepines

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **110**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization method: simple Registration of patients and their assignment in each group by An anesthesiologist and a person other than the person performing the project are performed Randomization unit: individual Random tool: statistical software Random allocation will be hidden in such a way that the assigned group is not known before the individual is assigned.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
This study is a double-blind clinical trial and the patient and the intern do not know the type of drug received for sedation.

**Placebo**  
Not used

**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Urmia University of Medical Sciences

**Street address**  
Corner of the alley 8, in front of the health center, Kashani St

**City**  
urmia

**Province**  
West Azarbaijan

**Postal code**  
5714614754

**Approval date**  
2022-03-15, 1400/12/24

**Ethics committee reference number**  
IR.UMSU.HIMAM.REC.1401.008

**Health conditions studied**

1

**Description of health condition studied**  
Patients under mechanical ventilation admitted to the intensive care unit

**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

1

**Description**  
Comparison of the sedative effect of lorazepam with midazolam

**Timepoint**  
Patients will be assessed at injection start times of 15 minutes, 30 minutes, 1 hour, 3 hours, 6 hours, and 12 hours after the start of the infusion.

**Method of measurement**  
During current study patients' demographic information (age and sex), body mass index, blood pressure, heart rate, respiratory rate, oxygen saturation( via pulse oximetry), level of consciousness (by Glasgow coma scale) and level of sedation ( by Richmond sedation scale and Ramsay sedation scale) will be recorded in a checklist prepared by the researcher. Also, the total amount of midazolam and lorazepam that will be used, their prices, duration of mechanical ventilation, duration of hospitalization ( either in intensive care unit or ward)

and the mortality rate of patients will be recorded.

## Secondary outcomes

### 1

#### **Description**

Richmond benchmark score

#### **Timepoint**

Patients will be evaluated at 15 minutes, 30 minutes, 1 hour, 3 hours, 6 hours, and 12 hours after the start of the infusion.

#### **Method of measurement**

- Aggressive, aggressive (fierce, militant, with violent and dangerous movements for themselves and others) +4- Very restless (aggressive, restless, kills tubes and catheters, dangerous for himself) +3- Restless (repetitive movements, aimless, fighting with mechanical ventilation) +2- Restless (has worries and fears, excited; but not aggressive and restless) +1- Calm-conscious (with normal movements and behavior) 0- Sleepy - confused (not fully awake but can stay awake for more than 10 seconds (make eye contact against sound for more than 10 seconds)) 1-- Slightly mild (slight (mild) drowsiness stays awake for less than 10 seconds (making eye contact against sounding less than 10 seconds)) 2-- Medium calm (opens his eyes, moves in the direction of sound but without eye contact) 3-Intense calm (does not respond to sound, but responds to the therapist's physical stimuli)- No response (does not respond to the therapist's voice and physical stimuli) 5-

### 2

#### **Description**

Ramsay scoring system

#### **Timepoint**

Patients will be evaluated at 15 minutes, 30 minutes, 1 hour, 3 hours, 6 hours, and 12 hours after the start of the infusion.

#### **Method of measurement**

Can not be assessed 0 is fully conscious 1 is drowsy, wakes up without stimulus 2 is drowsy, who wakes up with vocal stimulation 3 is drowsy and wakes up with a bang on the shoulder and loudly 4 is drowsy and wakes up with a bang on the face and a loud voice 5 is drowsy and does not respond to blows to the face and loud voice

### 3

#### **Description**

Glasgow Index

#### **Timepoint**

Patients will be evaluated at baseline and 15 minutes, 30 minutes, 1 hour, 3 hours, 6 hours, and 12 hours after infusion

#### **Method of measurement**

An index to report the severity of anesthesia in a person with a score of 4 to 15

### 4

#### **Description**

Body mass index

#### **Timepoint**

Start studying

#### **Method of measurement**

بر حسب Kg/m<sup>2</sup>

### 5

#### **Description**

Cause of intubation

#### **Timepoint**

Start studying

#### **Method of measurement**

Surgery, hypoxia, hypercapnia, etc.

### 6

#### **Description**

Cause of admission

#### **Timepoint**

Start studying

#### **Method of measurement**

Reason for patients to refer to the intensive care unit

### 7

#### **Description**

Type of medicine

#### **Timepoint**

End of study

#### **Method of measurement**

One of the two drugs lorazepam and midazolam will be injected for the patient

### 8

#### **Description**

Cost of medicine

#### **Timepoint**

End of study

#### **Method of measurement**

Rial

### 9

#### **Description**

side effects

#### **Timepoint**

Patients will be evaluated at 15 minutes, 30 minutes, 1 hour, 3 hours, 6 hours, and 12 hours after the start of the infusion.

#### **Method of measurement**

Forgetfulness, headache, excessive lethargy, pain, sleepiness, hypotension, pain and tenderness at the injection site, apnea, cough, slow breathing, hiccups, respiratory arrest, etc.

### 10

#### **Description**

Duration of mechanical ventilation

## Timepoint

Since intubation

## Method of measurement

By day

## 11

### Description

Mortality rate

### Timepoint

End of study

### Method of measurement

Died, alive

## Intervention groups

## 1

### Description

Intervention group: Group L patients will receive 2 mg of lorazepam every 2 hours for 12 hours (12 mg). The drug will be diluted and infused in 250 cc of normal saline 0.9%.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Group M patients will receive midazolam at a dose of 2 mg per hour for 12 hours (24 mg), the drug will be diluted and infused in 250 cc of normal saline 0.9%

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

بیمارستان امام خمینی ارومیه

#### Full name of responsible person

Amin Nourollahi

#### Street address

Imam Khomeini Hospital, Ershad St

#### City

urmia

#### Province

West Azarbaijan

#### Postal code

5714614754

#### Phone

+98 903 139 3078

#### Email

Amin1816@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Oroumia University of Medical Sciences

#### Full name of responsible person

Parvin Ayremlou

#### Street address

Imam Khomeini Hospital, Ershad St

#### City

urmia

#### Province

West Azarbaijan

#### Postal code

5751781351

#### Phone

+98 44 3348 5325

#### Email

Amin1816@yahoo.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

#### Full name of responsible person

Mohamadamin Valizadeh Hasanloui

#### Position

Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Anesthesiology

#### Street address

Imam Khomeini Hospital, Ershad St

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

5715781351

#### Phone

+98 44 3348 5325

#### Email

aminvalizade@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Mohamadamin Valizadeh Hasanloui

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Khomeini Hospital, Ershad St

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715781351

**Phone**

+98 44 3348 5325

**Email**

aminvalizade@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Amin Nourollahi

**Position**

Intern medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Corner of the alley 8, in front of the health center,  
Kashani St

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714614754

**Phone**

+98 903 139 3078

**Email**

amin1816@yahoo.com

## 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**

Yes - There is 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**

How to do the project and its final results will be published

**When the data will become available and for how long**

Access will start 3 months after the results are published

**To whom data/document is available**

The data will be available to the public

**Under which criteria data/document could be used**

Based on the results and data, the type of sedative for patients can be decided

**From where data/document is obtainable**

Amin Nourollahi executor of plan Email:  
Amin1816@yahoo.com

**What processes are involved for a request to access data/document**

The project and the data will be published in the form of articles. Researchers can have the necessary access by searching among the published articles.

**Comments**