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≥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/m2

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