Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the sedation effect of Dexmedetomidine and midazolam using the Richmond agitation sedation scale (RASS) in patients admitted to clinical toxicology intensive care unit

Protocol summary

Study aim

According to high prevalence of poisoning in Isfahan and the necessity of maintaining of airway by intubation which needs sedation before doing this procedure , And also both of Midazolam and Dexmedetomidine are safe and effective drugs for the sedation before intubation, we decided to compare the rate of sedation inducing by these drugs.

Design

This clinical trial has control group, with two parallel group, blinded and Random Allocation with two groups each including 30 people. for random allocation we use Random Allocation software.

Settings and conduct

In this study two people would be blinded, first the person who would fill the RASS scale forms, second the person who analyses the data. After random allocation into two groups each including 30 patients that admitted to ICU of poisoning patients in Khorshid hospital, we will give one group Dexmedetomidine and other group, Midazolam. then we measure the rate of sedation before and after taking drugs and intubation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with ASA class of III,IV admitted to ICU 2- Age between 18 to 80 3- Patients who are undergoing sedation before intubation 4- Not taking sedative drugs before admitting to ICU Non entry criteria: 1- Serum Creatinine more than 200 microMol/Lit 2- Allergy to any of the drugs used in this study 3- Patients with unstable angina or acute myocardial infarction 4- Advanced liver failure

Intervention groups

There would be two intervention group in this clinical trial that one of them would be taking Dexmedetomidine before intubation and the other group would be taking Midazolam. Then we use RASS scale to score the level of sedation that induced in patients.

Main outcome variables

1- Assessment and compare rate of sedation induced by each drugs by Richmond agitation-sedation scale (RASS) 2- Blood pressure measurement 3- Heart rate measurement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211022052838N1**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name
Arman Otroshi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3651 4261
Email address
arman.otroshi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the sedation effect of Dexmedetomidine and midazolam using the Richmond agitation sedation scale (RASS) in patients admitted to clinical toxicology intensive care unit

Public title
Comparison between sedating effect of Midazolam and Dexmedetomidine in intubated poisoned patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with American society of anesthesiologist (ASA) class 3 and 4 who are admitted in ICU of poisoned patients Age between 18 to 80 Patients whom are going to be intubated Not taking sedative drugs before admitting to intensive care unit (ICU)
Exclusion criteria:
known allergy to any of the drugs used in this study advanced liver disease Serum creatinine level above 200 micromol/liter Unstable angina or acute myocardial infarction patients
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random allocation of eligible people into two groups is done by Random allocation software. There are several boxes in this software: the number of groups, the total number of samples. After specifying the number of groups (2) and the total number of samples (60), the software randomly divides the entire sample into two groups of 30.
Blinding (investigator's opinion)
Double blinded
Blinding description
According to the randomization done by the software, the main author of the plan (professor) knows which patient will take which of the drug categories and injects the ampoule containing the sedative drug to the patient, while the patient does not know which of the two drugs, has received. Then the outcome assessor (student) comes to the patient's bedside and fills the RASS form without knowing what medicine the patient has taken. Then the information and forms are provided to the data analyst without knowing which medicine the patient has received, and after the analysis, he provides the information to the main author of the plan.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan university of medical sciences
Street address
Isfahan university of medical sciences, isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-04-04, 1402/01/15
Ethics committee reference number
IR.MUI.MED.REC.1402.024

Health conditions studied

1

Description of health condition studied
Sedation before Intubation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of sedation caused by drug according to RASS scale
Timepoint
Before intervention and then every 2 hours
Method of measurement
RASS scale system is a known scale in the world that measured the rate of sedation whom admitted to ICU. Scoring points in this scale include -5 to +4 that the +4 point belongs to agitated and aggressive patients who are a threat for ICU personals. the -5 points belongs to the patients who are not responding to voice and

physical stimulations and they are not conscious. the rest of points are spectrum between these two scores.

2

Description
Blood pressure in the admitted patients of ICU
Timepoint
Before intervention and then every 2 hours
Method of measurement
Vital sign monitoring device

3

Description
Heart rate
Timepoint
Before intervention and then every 2 hours
Method of measurement
Vital sign monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients admitted to Intensive care unit (ICU) of poisoned patients
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid hospital
Full name of responsible person
Arman Otroshi
Street address
Khorshid medical educational research complex, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8145833117
Phone
+98 31 3222 2127
Email
nobakht9877@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Arman Otroshi
Street address
Isfahan university of medical sciences, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
nobakht9877@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Arman Otroshi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Toxicology
Street address
Elahie apartment. No2 avenue. No9 Street.shahed Blvd. Sepahan Shahr .Isfahan
City
Isfahan
Province
Isfehan
Postal code
0000000000
Phone
+98 31 3651 4261
Email

arman_otroshi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Arman Otroshi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Toxicology

Street address
Elahie apartment. No2 avenue. No9 Street.shahed Blvd. Sepahan Shahr .Isfahan

City
Isfahan

Province
Isfehan

Postal code
0000000000

Phone
+98 31 3651 4261

Email
Arman_otroshi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Position
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City
Isfahan

Province
Isfehan

Postal code
000000000

Phone
+98 31 3651 4261

Fax

Email
arman.otroshi@med.mui.ac.ir

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