

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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

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Email address

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

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

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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