

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Efficacy and safety of two drugs, midazolam, and dexmedetomidine, on the sedation of mechanically ventilated children

#### Protocol summary

##### Study aim

Comparison of two drugs, midazolam, and dexmedetomidine, in the sedation of children under mechanical ventilation

##### Design

A parallel-group, single-blind, randomized, phase 1 clinical trial on 124 patients. Randomization sequence generation using [www.randomization.com](http://www.randomization.com) Allocation concealment will be done using opaque and numbered envelopes.

##### Settings and conduct

Children aged 1 month to 18 years who are admitted to the pediatric intensive care unit of Akbar Hospital, Ghaem Hospital, and Sheikh Hospital and undergo mechanical ventilation. The study is one-sided blind (person analyzing the data).

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: Mechanically ventilated children aged 1 month to 18 years who were admitted to the intensive care unit of Akbar Hospital will be included in the study. Criteria for not entering the study: Suffering from dysfunction of the central nervous system, whether genetic or acquired

##### Intervention groups

Dexmedomidine is injected intravenously. The bolus dose of the drug will be 0.5 micrograms per kilogram and the starting dose of the infusion will be 0.25 micrograms per kilogram per hour. While evaluating every 15 minutes, if the sedation level is lower than the target level, 0.25 micrograms per kilogram per hour will be added to the drug dose at each turn, up to a maximum of 1 microgram per kilogram per hour.

##### Main outcome variables

The rate of treatment failure and the need for a second sedative drug

#### General information

##### Reason for update

Title: Both efficacy and safety of two drugs have been evaluated. Phase: Phase 1 clinical trial. Sample size: According to the sample size formula in the proposal, a typo has been occurred during recording the proposal. Research environment: Patients admitted to the ICU due to the large sample size and homogeneity of patients in the three centers of Akbar, Ghaem, and Sheikh, sampling was conducted from three centers. Evaluation: To prevent bias, evaluation was performed every 15 minutes. Secondary outcome: Re-evaluation of Ramsay score in successful patients at 6 h later in follow-up.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190522043672N3**  
Registration date: **2023-02-16, 1401/11/27**  
Registration timing: **registered\_while\_recruiting**

Last update: **2025-05-03, 1404/02/13**

Update count: **1**

##### Registration date

2023-02-16, 1401/11/27

##### Registrant information

###### Name

Majid Sezavar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3870 9225

###### Email address

sezavardm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-09, 1401/11/20

##### Expected recruitment end date

2024-02-09, 1402/11/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy and safety of two drugs, midazolam, and dexmedetomidine, on the sedation of mechanically ventilated children

**Public title**

Efficacy and safety of two drugs, midazolam and dexmedetomidine, in sedation of children

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Suffering from dysfunction of the central nervous system, whether genetic or acquired

**Exclusion criteria:**

Having bradycardia Resistant hypotension during treatment

**Age**

From **1 month** old to **18 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **124**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization sequence generation using [www.randomization.com](http://www.randomization.com) For 124 people, it will be coded A and B, and the allocation will be concealed using a coded and numbered sealed envelope.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The plan's statistical consultant who analyzes the data does not have information about the type of drug.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9195965919

**Approval date**

2023-01-21, 1401/11/01

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1401.537

**Health conditions studied****1****Description of health condition studied**

Other side effects of anesthesia and sedation

**ICD-10 code**

T88.5

**ICD-10 code description**

Other complications of anesthesia

**Primary outcomes****1****Description**

The rate of treatment failure and the need for a second sedative drug

**Timepoint**

The first day, the second day and the third day of the intervention

**Method of measurement**

Using the Ramsay score table

**Secondary outcomes****1****Description**

Duration of reaching target sedation

**Timepoint**

The first, second and third day of the intervention

**Method of measurement**

Measuring time with a timer

**2****Description**

Duration of mechanical ventilation

**Timepoint**

The day of the patient's discharge

**Method of measurement**

patient file

### 3

**Description**

Bradycardia

**Timepoint**

daily during the intervention period

**Method of measurement**

Doctor supervision and clinical monitor

### 4

**Description**

Hypotension

**Timepoint**

daily during the intervention period

**Method of measurement**

Mercury sphygmomanometer

### 5

**Description**

Mortality rate

**Timepoint**

The last day of hospitalization

**Method of measurement**

patient file

### 6

**Description**

Duration of stay in PICU

**Timepoint**

The day of the patient's discharge

**Method of measurement**

patient file

### 7

**Description**

Re-evaluation of Ramsay score in successful patients at 6 hour later in follow-up

**Timepoint**

in follow-up

**Method of measurement**

Ramsay sedation scale

## Intervention groups

### 1

**Description**

Intervention group: Dexmedomidine is injected intravenously. The bolus dose of the drug will be 0.5 micrograms per kilogram and the starting dose of the infusion will be 0.25 micrograms per kilogram per hour. While evaluating every 15 minute, if the sedation level is lower than the target level, 0.25 micrograms per kilogram per hour will be added to the drug dose at each turn, up to a maximum of 1 microgram per kilogram per hour.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Children from 1 month to 15 years who are under mechanical ventilation in the intensive care unit and are injected intravenously with midazolam for sedation. The bolus dose of the drug will be 0.15 mg per kilogram and the starting dose of the infusion will be 1 microgram per kilogram per minute. While evaluating every one hour, if the level of sedation is lower than the target level, 1 microgram per kilogram per minute will be added to the drug dose at each turn, up to a maximum of 4 micrograms per kilogram per minute. If we do not reach the target sedation level with the maximum dose, the treatment will be considered a failure and the second sedative drug will be added

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Akbar Children's Hospital

**Full name of responsible person**

Majid Sezavar

**Street address**

Akbar Children's Hospital, Shahid Kaveh 14, Shahid Kaveh Boulevard

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177897157

**Phone**

+98 51 3870 9225

**Email**

sezavardm@mums.ac.ir

### 2

**Recruitment center****Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Majid Sezavar

**Street address**

Ahmadabad Ave.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3845 3239

**Email**

Sezavardm@mums.ac.ir

### 3

#### Recruitment center

**Name of recruitment center**

Sheikh Hospital

**Full name of responsible person**

Majid Sezavar

**Street address**

Dr. Sheikh Ave., Tohid Square

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**Province**

Razavi Khorasan

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9139963185

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**Email**

sezavardm@mums.ac.ir

### Sponsors / Funding sources

#### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Majid Ghayor Mobarhan

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Mashhad

**Province**

Razavi Khorasan

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1394491388

**Phone**

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**Email**

GhayourM@mums.ac.ir

**Grant name**

Grant from Mashhad University of Medical Sciences

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Sezavar

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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akbar hospital.Mashhad University of Medical Sciences, Mashhad, Iran

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**Email**

sezavardm@mums.ac.ir

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Sezavar

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**City**

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**Email**

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### Person responsible for updating data

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Sezavar

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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**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**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The main and secondary results can be shared.

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

Six months after the results are published

**To whom data/document is available**

Researchers affiliated with academic centers

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

Researchers affiliated with academic centers

**From where data/document is obtainable**

Dr.Majid Sezavar

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

Request via email to sezavardm@mums.ac.ir

**Comments**