

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### comparing longterm infusion of dexmedetomidin versus midazolam in mechanically ventilated patients admitted to intensive care unit

#### Protocol summary

##### Summary

The aim of this study was to compare the long-term infusion of Dexmedetomidin versus midazolam in mechanically ventilated patients admitted to the intensive care unit. Twenty patients will be enrolled in each group. Patients will be randomly divided into two groups. Patients in Group Dexmedetomidin will receive 0.4 to 0.8 micrograms per kilogram per hour of Dexmedetomidin to achieve a RASS between -1 to -2. Patients in Group midazolam will receive 0.02 to 0.04 milligrams per kilogram of midazolam to achieve the RASS between -1 to -2. To assess patient consciousness, washout period (interruption of sedation) from 7 am until 9 am will be done in all patients. The purpose of this evaluation will be the assessment of 4 task including opening of the eyes with calling, follow-up of researchers and clinicians with eyes, hand pressure and protrusion of the tongue. For all patients, the time needed to reach the target RASS, ration of duration of time spent in target RASS to total duration of sedation, need to increasing the drug dose or addition of other sedative medications will be recorded. The primary outcome variable is duration of mechanical ventilation and the secondary outcome variable is length of ICU stay and mortality are.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201608192582N16**

Registration date: **2016-11-08, 1395/08/18**

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

Last update:

Update count: **0**

##### Registration date

2016-11-08, 1395/08/18

#### Registrant information

##### Name

Ata Mahmoodpoor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 116 0888

##### Email address

mahmoodpoora@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

vice chancellor for research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2016-09-22, 1395/07/01

#### Expected recruitment end date

2017-12-22, 1396/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

comparing longterm infusion of dexmedetomidin versus midazolam in mechanically ventilated patients admitted to intensive care unit

#### Public title

comparing infusion of dexmedetomidin versus midazolam in patients admitted to intensive care unit

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

inclusion criteria: all patients with more than 18 years old who need to be admitted to ICU and ungergone

mechanical ventilation exclusion criteria: allergy to recital drug; needing the infusion of both drugs; resistant to treatment hypotension; pregnancy or lactation; addiction history; CNS disease; dialysis history; hepatic function disorder; EF<30%

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Golgasht street

**City**

Tabriz

**Postal code****Approval date**

2016-07-25, 1395/05/04

**Ethics committee reference number**

IR.TBZMED.REC.1395.406

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

unconsciousness

**ICD-10 code**

G96.9

**ICD-10 code description**

Disorder of central nervous system, unspecified

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

duration of mechanical ventilation

**Timepoint**

Daily

**Method of measurement**

counting the days under mechanical ventilation

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

ICU length of stay

**Timepoint**

daily

**Method of measurement**

counting days of ICU stay

**2****Description**

mortality

**Timepoint**

daily

**Method of measurement**

counting mortality

**Intervention groups****1****Description**

intervention group dexmedetomidine 0.4-0.8 µg/kg/h

**Category**

Treatment - Drugs

**2****Description**

control group Midazolam 0.02-0.04 mg/kg

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

General ICU of Imam Reza hospital

**Full name of responsible person**

Ata Mahmoodpoor

**Street address**

General ICU, Imam Reza hospital

**City**

Tabriz

**2**

**Recruitment center**

**Name of recruitment center**

ICU of Shohada hospital

**Full name of responsible person**

Ata Mahmoodpoor

**Street address**

ICU, Shohada hospital

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research of Tabriz University of Medical Sciences

**Full name of responsible person**

Afshin Ghalehgalab Behbahani

**Street address**

Tabriz University of Medical Sciences, Golgasht street

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Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research of Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Nina Pilevar

**Position**

Anesthesiology Resident

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*