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 miligrams 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

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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 hypotention; 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
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ICU, Shohada hospital
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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 Ghalehgolab Behbahani
Street address
Tabriz University of Medical Sciences, Golgasht street
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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
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
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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