Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral Gabapentin on sedative consumption in mechanically ventilated patients in intensive care unit

Protocol summary

Study aim

Evaluation of the effectiveness of oral gabapentin on the use of sedative medications in patients undergoing mechanical ventilation in intensive care units in order to design a method for reducing the use of sedative medications in ICU

Design

In Imam Hossein Hospital, during a 6 month period we categorize all patients in ICU who are under mechanical ventilation and meet the inclusion criteria into two groups of intervention (administration of gabapentin) and control (placebo) based on block randomization The present study is triple-blinded, so that the ICU nurse, the second ICU attending and the patient are not aware of the type of medication or placebo. To this end, the first ICU attending identifies eligible patients to be recruited into the study. The objectives of the study are explained to the patient's eligible family member and if they are willing to participate in the research project, written consent will be obtained from them.

Settings and conduct

This is a randomized 3-blinded clinical trial conducted at Imam Hossein Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.patients with at least 18 years of age . 2. patients under mechanical ventilation for more than 3 days Exclusion criteria: 1.Renal Disease 2. A history of acute neurological condition or neuromuscular disease. 3. haemodynamic instability

Intervention groups

In Imam Hossein Hospital, during a six month period we categorize all patients in ICU who are under mechanical ventilation and meet the inclusion criteria into two groups of intervention (administration of gabapentin) and control (placebo).

Main outcome variables

Midazolam and Fentanyl consumption

General information

Reason for update

The "expected recruitment start date" and consequently the "expected recruitment end date" were written based on the code of ethics issuance date, while the start of patient recruitment was expected and organized to commence from 1st May 2019 which is after the issuance of IRCT Code . Therefore other related items were updated as well, namely the "Actual recruitment start date", "Actual recruitment end date", and "Trial completion date" respectively.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042588N1**
Registration date: **2019-04-28, 1398/02/08**
Registration timing: **prospective**

Last update: **2020-02-04, 1398/11/15**
Update count: **1**

Registration date

2019-04-28, 1398/02/08

Registrant information

Name
Sara Salarian
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2665 1601
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sarasalarian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-01, 1398/02/11

Expected recruitment end date

2019-12-20, 1398/09/29

Actual recruitment start date

2019-05-01, 1398/02/11

Actual recruitment end date

2019-12-20, 1398/09/29

Trial completion date

2019-12-20, 1398/09/29

Scientific title

The effect of oral Gabapentin on sedative consumption in mechanically ventilated patients in intensive care unit

Public title

The effect of oral Gabapentin on sedative consumption in mechanically ventilated patients in intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1. Age should be ove18 years of age. 2. Mechanical ventilation for more than 3 days

Exclusion criteria:

1. Renal failure. 2. Acute neurological disease and Neuromuscular disease. 3. Unstable Hemodynamic

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a triple-blind study, so that the nurse of the department, the second assistant professor of ICU and the patient are not aware of the type of medication or placebo. To this end, firstly, by the first assistant professor of the ICU determines the patients eligible for inclusion in the study are by random numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

And the relevant nurse will be given instructions on how to evaluate the sedation in each group. But he does not know the type of medicine. The second Assistant Professor of ICU assesses the patient's severity score, but does not know the type of medication.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ṡhahid Beheshti University of Medical Sciences

Street address

Imam Hossein Hospital, Madani Str, Tehran, Iran. Post Code

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.836

Health conditions studied

1

Description of health condition studied

Dependence on respirator [ventilator] status

ICD-10 code

Z99.11

ICD-10 code description

Dependence on respirator [ventilator] status

Primary outcomes

1

Description

Fentanyl consumption

Timepoint

daily

Method of measurement

microgram/kilogram/hour

2

Description

Midazolam consumption

Timepoint

Daily

Method of measurement

milligram/kilogram

3

Description
Gabapentin prescribed dosage
Timepoint
Daily
Method of measurement
milligram

Secondary outcomes

1

Description
Number of days under ventilation
Timepoint
Daily
Method of measurement
Nursing Report

2

Description
Ramsay scale score
Timepoint
hourly
Method of measurement
Scale Score

Intervention groups

1

Description
Intervention group: In this group, the fixed dose of Gabapentin (300mg TDS, daily) dissolved in 5cc normal saline is administered through nasogastric tube , and then, if necessary, with the aim of maintaining an Ramsay Score Scale rating of between 2 and 3, fentanyl 0.5 - 2 µg / kg / hr) and midazolam (0.05-0.1 mg / kg) are given intravenously.
Category
Treatment - Drugs

2

Description
Control group: For the control group, the placebo solution which is dissolved in 5 ml of normal saline will be prescribed via NGT, and then, if necessary, with the aim of maintaining the rate of the RSS between 2 to 3, Fentanyl (0.5-2 µg / kg / hr) and Midazolam (0.05-0.1 mg / kg) will be prescribed intravenously
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein Medical and Educational Center
Full name of responsible person
Sara Salarian
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Shahid Arabi Str, Yemen Str
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1985717443
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Email
mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Sara Salarian
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Yes - There is 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
Title and more details about the data/document
The whole potential data after being unidentifiable is published
When the data will become available and for how long
From 1400
To whom data/document is available
Medical Society
Under which criteria data/document could be used
Contributing to studies
From where data/document is obtainable
sarasalarian@sbmu.ac.ir
What processes are involved for a request to access data/document
two months
Comments