

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)

Phone

+98 21 2665 1601

Email address

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 over 18 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 Shahid 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

Shahid Madani Str

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7755 8001

Email

sarasalarian@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Arabi Str, Yemen Str

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2387 2202

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
Anesthesiology
Street address
Shahid Madani Str
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7755 8001
Email
sarasalarian@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elham Memari
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Madani Str
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 73430
Email
drmemory@sbmu.ac.ir

Person responsible for updating data

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
Anesthesiology
Street address
Shahid Madani Str
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7755 8001
Email
sarasalarian@sbmu.ac.ir

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