Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of gabapentin against clonidine in reducing the dose of sedation in patients with mechanical artificial ventilation

Protocol summary

Study aim
Comparison of the effect of gabapentin with clonidine in reducing the dose of fentanyl for sedation in mechanically ventilated patients

Design
Sampling will be done by the available method, then according to the calculation, 30 people in each group will be randomly assigned to the class (for matching in terms of gender, age). For this purpose, during 6 months in Imam Hossein Hospital, Intensive Care Unit, all patients with endotracheal tubes who are under mechanical ventilation and have the conditions to enter the study are divided into three categories based on the table of random numbers. We group one group of gabapentin tablets three times a day and one group of clonidine tablets four times a day, and the third group is given midazolam, which is our control group, we gavage and fentanyl is prescribed in all three groups. The amount of fentanyl required to achieve sedation in the range of 3 to 4 cryptographic points is recorded in three groups and finally compared.

Settings and conduct
The study is a clinical trial and will be performed in the intensive care unit of Imam Hossein Hospital.

Participants/Inclusion and exclusion criteria
Age over 18 years and patients connected to mechanical ventilation

Intervention groups
We give a group of gabapentin 300 mg tablets three times a day and a group of 0.1 mg clonidine tablets four times a day, and the third group is given midazolam micro 20 to 100 kg per kilogram, which is our control group. Fentanyl is administered as PRN in all three groups at 25 to 200 micrograms per hour of infusion. The amount of fentanyl required to achieve sedation in the range of 3 to 4 cryptographic points is recorded in three groups and finally compared.

Main outcome variables
Adjusting Opioide use

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210405050848N2**
Registration date: **2021-06-13, 1400/03/23**
Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**
Update count: **0**

Registration date
2021-06-13, 1400/03/23

Registrant information

Name
Jafar Vakili

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of gabapentin against clonidine in reducing the dose of sedation in patients with mechanical artificial ventilation

Public title
Adjusting opioide use
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Patients connected to a mechanical ventilator
Exclusion criteria:
History of Clonidine allergy History of Gabapentine allergy
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
After the entry of participants according to the inclusion criteria, the pre-test will be performed using a cryptographic evaluation checklist, then randomly assigned by the head nurse based on blocking. Given that 90 people must be included in the study and there will be three groups (gabapentin, clonidine and control), taking into account all possible possibilities, the number of blocks will be calculated (it is necessary to explain that the number of blocks of the compound formula : C (n, r) = C_r ^ n = n C r = (n¦r) will be obtained).
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind. The medicine is prescribed by a doctor and injected by a nurse and recorded in a checklist. The patient and the researcher have no role in randomly assigning the samples to the intervention or control group, and the intervention will be performed and the results will be recorded by the relevant nurse. The samples will be analyzed by a doctor. The interpretation of the data will be done by the researcher and will be decided based on the interpreted results.
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
th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Province
Tehran
Postal code
1985717443
Approval date
2021-05-11, 1400/02/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.018

Health conditions studied

1

Description of health condition studied
Adjust opioid use
ICD-10 code
Opioid ove
ICD-10 code description
Opioid overdose

Primary outcomes

1

Description
Sedation of patients connected to a mechanical ventilator
Timepoint
Before and after medication
Method of measurement
Ramsay score

Secondary outcomes

1

Description
Adjustment Opioide use
Timepoint
Before and after medication
Method of measurement
Ramsay score

Intervention groups

1

Description
Intervention group: Gabapentin 300 mg tablets are gavaged three times a day. Fentanyl ampoules are also given as a PRN at 25 to 200 micro / hour infusion. We record the need for fentanyl to achieve sedation in the range of 3 to 4 groups and finally compare.

Category
Treatment - Drugs

2

Description
Intervention group: Clonidine 0.1 mg of clonidine tablets four times a day. Fentanyl ampoules are also given as a PRN at 25 to 200 micro / hour infusion. We record the need for fentanyl to achieve sedation in the range of 3 to 4 groups and finally compare.

Category
Treatment - Drugs

3

Description
Control group: The ampole of midazolam is injected at 20 to 100 microbes per kilogram. Fentanyl ampoles are also given as a PRN at 25 to 200 micro / hour infusion. We record the need for fentanyl to achieve sedation in the range of 3 to 4 groups and finally compare.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hosein Hospital

Full name of responsible person
Jafar Vakili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zargi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Jafar Vakili

Position
Fellowship of ICU

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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