Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the effect of dexmedetomidine vs midazolam infusion on the agitation level and hemodynamic changes in patients with non-traumatic ICH and IVH caused by hypertension in patients admitted to the ICU

Protocol summary

Study aim

Comparison of the effect of dexmedetomidine infusion against midazolam on the level of agitation and hemodynamic changes in patients with HICH and HIVH intubated in ICU

Design

A clinical trial with two parallel groups, double-blind, randomized, phase 4 on 68 patients who were randomly divided by Excel's rand function.

Settings and conduct

after ICU admission and intubation, the patients will be divided into two groups secretly and will receive sedative drugs with the mentioned dose. Then the data collectors record the results of the study blindly.

Participants/Inclusion and exclusion criteria

Patients suspected of ICH or IVH will be included in the study after confirming the disease and obtaining consent from the patient or his legal guardian. The inclusion criteria are: having ICH or IVH due to high blood pressure; ICU admission; Necessity of intubation; being at least 18 years old Exclusion criteria are: heart rate less than 60; lack of patient sedation even with the maximum dose of midazolam and dexmedetomidine; MAP less than or equal to 7

Intervention groups

The midazolam group will receive 2mg of midazolam and the patients in the dexmedetomidine group will receive 0.5mg/kg of dexmedetomidine within 10 minutes. After receiving the first dose, the anesthesiologist will determine the amount of drug infusion based on the patient's sedation conditions and Ramsay Sedation Score. The minimum and maximum infusion rates in the midazolam group will be between 1 and 2 mg/hour and in the dexmedetomidine group between 0.2 and 0.5 mg/kg/hour.

Main outcome variables

Ramsay Sedation Scale and hemodynamic factors of the patient including heart rate, spo2 and mean arterial pressure and the amount of narcotic required in the first 30 minutes after entering the ICU and then 1 hour, 2 hours, 3 hours, 6 hours, 18 hours and 24 hours. Hours after arrival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230101057010N1**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Misagh Rostami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of dexmedetomidine vs midazolam infusion on the agitation level and hemodynamic changes in patients with non-traumatic ICH and IVH caused by hypertension in patients admitted to the ICU

Public title

Comparison of the effect of dexmedetomidine vs midazolam infusion on the agitation level and hemodynamic changes in patients with hypertension-caused ICH and IVH

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ICH or IVH due to high blood pressure ICU admission Patient intubation be at least 18 years old Consent of the patient or legal guardian in terms of entering the study

Exclusion criteria:

A heart rate of less than 60 is excluded from the study after receiving atropine. If the patient is not sedated with the maximum dose of midazolam and dexmedetomidine (Ramsay Sedation Scale above 4), the patient will be prescribed narcotics and will be excluded from the study. MAP less than or equal to 7 Lack of consent of the patient or legal guardian

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

68 intubated patients suffering from non-traumatic ICH and IVH caused by hypertension who were admitted to the ICUs of Shahid Madani Hospital in Karaj in 2023 were selected for the study, and with the help of rand function of Excel software we randomly divide the individual into two groups: midazolam and dexmedetomidine (34 people each).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and their legal guardians are included in the study without knowing the type of sedative drug. Also, those responsible for data collection will be unaware of the type of medication the patient received, and the medication will only be known to the attending physician and ICU nurses.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

alborz university of medical sciences

Street address

Taleghani Blvd

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2023-10-07, 1402/07/15

Ethics committee reference number

IR.ABZUMS.REC.1402.186

Health conditions studied

1

Description of health condition studied

Nontraumatic intracranial hemorrhage

ICD-10 code

I62.9

ICD-10 code description

Nontraumatic intracranial hemorrhage, unspecified

Primary outcomes

1

Description

Agitation level

Timepoint

It will be measured and recorded at different times, including upon arrival, the first 30 minutes after entering the ICU, and then 1 hour, 2 hours, 3 hours, 6 hours, 18 hours, and 24 hours after entering the ICU.

Method of measurement

Ramsay Sedation Scale

Secondary outcomes

1

Description
vital sign
Timepoint
Upon arrival, the first 30 minutes after entering the ICU and then 1 hour, 2 hours, 3 hours, 6 hours, 18 hours and 24 hours after entering the ICU will be assessed and recorded.
Method of measurement
Blood pressure measuring device, pulse oximeter, thermometer

2

Description
The need to use narcotic drugs to maintain sedation
Timepoint
Upon arrival, the first 30 minutes after entering the ICU and then 1 hour, 2 hours, 3 hours, 6 hours, 18 hours and 24 hours after entering the ICU will be assessed and recorded.
Method of measurement
Ramsay Sedation Scale

Intervention groups

1

Description
Intervention group: Dexmedetomidine: This drug is a selective alpha-2-adrenoceptor agonist that can calm patients hospitalized in ICU and is available in 100MCG/2ML vials. Patients in this group will receive an infusion of 0.5 mg/kg of this drug over 10 minutes upon arrival in the ICU. Then the maintenance dose will be 0.2 to 0.5 mg/kg per hour based on the amount of sedation.
Category
Treatment - Drugs

2

Description
Intervention group: Midazolam: This drug is a relatively short-acting benzodiazepine drug that has anti-anxiety and sedative effects and can calm patients hospitalized in ICU, and in this study, 5mg/1ml ampoules of this drug will be used. Patients in this group will receive an infusion of 2 mg of this drug over 10 minutes upon arrival in the ICU. Then the maintenance dose will be 1 to 2 mg per hour based on the amount of sedation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Hospital Karaj
Full name of responsible person
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Sponsors / Funding sources

1

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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
Karaj 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All potential data, including the data file of the participants, the informed consent form, and the study protocol will be shared after de-identifying people, according to the protocols of Alborz University of Medical Sciences.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data of this study will be available to perform analyzes related to the safety and efficacy of the investigated drugs.
From where data/document is obtainable
Dr. Sevak Hatmian
What processes are involved for a request to access data/document
The information will be accessible after being reviewed by the research vice-chancellor of Alborz University of Medical Sciences
Comments