

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Country

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

Sevak Hatamian

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Mahan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Karaj University of Medical Sciences

Full name of responsible person

Misagh Rostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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