

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Compare effects propofol and dexmedetomidine in hemodynamic Changes and delirium in trauma patients in the ICU

Protocol summary

Study aim

Comparing the effects of propofol and dexmedetomidine on hemodynamic changes and delirium in trauma patients

Design

Settings and conduct

In the ICU of Ali Bin Abitalib Hospital in Rafsanjan

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study include all trauma patients in the ICU, and the age range of 18-55 years and the presence of an informed companion are considered as inclusion criteria. They are randomly distributed And the exclusion criteria include patients with unstable hemodynamics and drug sensitivity to propofol (due to the possibility of delayed seizures, the patient should be cared for until one day after the operation) as well as patients with a history of drug abuse, drug abuse, or Alcohol dependence, history of neurological, neuromuscular or psychiatric diseases, especially history of seizures or epilepsy, history of pulmonary and cardiovascular diseases, long-term and chronic use of pain relievers including cyclooxygenase 2 inhibitors are also excluded from the study.

Intervention groups

There are 40 trauma patients with an age range of 18-55 years

Main outcome variables

Hemodynamic changes and delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190117042390N2**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **retrospective**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Seed hamid Pakzad moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

dr.pakzad@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-16, 1401/06/25

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

2023-03-16, 1401/12/25

Actual recruitment end date

2023-03-16, 1401/12/25

Trial completion date

2023-03-16, 1401/12/25

Scientific title

Compare effects propofol and dexmedetomidine in hemodynamic Changes and delirium in trauma patients in the ICU

Public title

Compare effects propofol and dexmedetomidine in hemodynamic Changes and delirium in trauma patients in the ICU of Ali Ebn Abitaleb Hospital of Rafsanjani years 2023

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The entry criteria for the study, including all people with trauma in the ICU, and the age range of 18-55 years and the presence of a companion, will be considered as the entry criteria. They are distributed randomly

Exclusion criteria:

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling was simple random and until the completion of the sample size among eligible clients. Then, the samples are divided into two similar groups of 20 people, dexmedetomidine and propofol, using the table of random numbers. And they are divided into two groups D and P and they are placed in one of the two groups according to the order of entry into the study (even and odd).

Blinding (investigator's opinion)
Single blinded

Blinding description
There are 40 trauma patients with an age range of 18-55 years. The study subjects will be divided into two groups of 20 people receiving dexmedetomidine and propofol, and hemodynamic changes and delirium will be investigated.

Placebo
Used

Assignment
Crossover

Other design features
And the exclusion criteria include patients with unstable hemodynamics and drug sensitivity to propofol (due to the possibility of delayed seizures, the patient should be cared for until one day after the operation) as well as patients with a history of drug abuse, drug abuse, or Dependence on alcohol, history of neurological, neuromuscular or psychiatric diseases, especially history of seizures or epilepsy, history of pulmonary and cardiovascular diseases, long-term and chronic use of pain relievers including cyclooxygenase 2 inhibitors are also excluded from the study. used in This research consists of: 1- Propofol with the brand name Pofol (it is a drug that is used by short-acting intravenous injection method and causes a decrease in the level of consciousness or anesthesia. This drug is used to start anesthesia and also maintain anesthesia during surgery. and in the form of 20ml ampoules containing 1%

propofol. Due to the use of emulsion, soy and egg, a history of sensitivity to these substances can indicate sensitivity to propofol. 2- Dexmedetomidine, which is a sedative drug and is used in patients who are carefully are under medical care and require mechanical ventilation. Dexmedetomidine is administered as a slow intravenous injection by the medical staff using a slow drug injection device, and it contains 200 mg of dexmedetomidine in ampoules of 20 ml.

Secondary Ids

1

Registry name

مرکز تحقیقات عوامل اجتماعی موثر بر سلامت

Secondary trial Id

401014

Registration date

2023-04-18, 1402/01/29

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Meraj - Alley65

City

Rafsanjan

Province

Kerman

Postal code

7737144559

Approval date

2022-09-14, 1401/06/23

Ethics committee reference number

IR.RUMS.REC.1401.178

Health conditions studied

1

Description of health condition studied

head trauma patients

ICD-10 code

S00-S09

ICD-10 code description

تروما به سر

2

Description of health condition studied

thorax trouma

ICD-10 code

520-529

ICD-10 code description

ترومای قفسه سینه

Primary outcomes

1

Description

Hemodynamic changes and delirium

Timepoint

3 months

Method of measurement

This study is a clinical trial study that will be conducted on 40 trauma patients with an age range of 18-55 years, divided into two groups, that is, under anesthesia with propofol and under anesthesia with dexmedetomidine. In the end, 20 people from each group will be tested for a total of 40 people. Considering the first type error of 5% and the power of 80% and the ability to show the average difference between the two groups that is statistically significant (size effect = 0.5), 20 cases were considered for each group.

Secondary outcomes

1

Description

Hemodynamic changes and delirium

Timepoint

16-12-24-48 hours after starting the drug

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Two groups of 20 people receiving dexmedetomidine and propofol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Bin Abitalib Hospital

Full name of responsible person

Hamid Pakzad Moghadam

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St 64 Meraj

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https://www.rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Seyed Hamid Pakzad

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
hamid pakzad moghadam
Position
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Latest degree
Subspecialist
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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

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

If the request is received, the desired information will be sent via email

When the data will become available and for how long

Up to one year after publication

To whom data/document is available

hamid pakzad

Under which criteria data/document could be used

If there is a request from official sources to use new research in line with the topic under study

From where data/document is obtainable

Send to the responsible author's email

What processes are involved for a request to access data/document

Sending to email, checking and verifying the test and resending to the requester

Comments