

# 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)

###### Phone

+98 34 3428 5983

###### 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

##### Street address

St 64 Meraj

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7737144459

##### Phone

+98 913 156 4386

##### Fax

+98 34 3428 0038

##### Email

pakzadmoghadam@gmail.com

##### Web page address

<https://www.rums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Seyed Hamid Pakzad Moghadam

##### Street address

North Meraj 64

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7737144459

##### Phone

+98 913 156 4386

##### Fax

+98 34 3428 0038

##### Email

pakzadmoghadam@gmail.com

##### Web page address

<https://www.rums.ac.ir>

#### 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

Anesthesiology  
**Street address**  
Meraj 64  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7737144459  
**Phone**  
+98 34 3428 0042  
**Email**  
pakzadmoghadam@gmail.com  
**Web page address**  
<https://www.rums.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
hamid pakzad moghadam  
**Position**  
Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
meraj 64  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7737144459  
**Phone**  
+98 34 3428 0042  
**Email**  
pakzadmoghadam@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
hamid pakzad  
**Position**

Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
meraj64  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7737144459  
**Phone**  
009834340042  
**Email**  
pakzadmoghadam@gmail.com

## 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