

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Ketamine and Dexmedetomidine in Maintenance of Anesthesia with Bispectral Index Scale during General Anesthesia

#### Protocol summary

##### Study aim

Comparison of ketamine and dexmedetomidine in maintaining the depth of anesthesia

##### Design

This study will be a double-blind randomized clinical trial on 90 patients referred to Peymaniyeh Hospital in Jahrom who undergo surgery under anesthesia. Patients participating in the study will be divided into three groups by a table of random numbers.

##### Settings and conduct

Patients referred to Peymaniyeh Hospital in Jahrom who will undergo surgery under general anesthesia in less than an hour will be included in the study. The study participant, researcher, and data collector will be unaware of the type of drug being used.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Peymaniyeh Hospital in Jahrom must be candidates for general anesthesia in less than one hour and express their consent to participate in the study. Non-entry conditions: includes patients who do not have hemodynamic stability and have renal disorders.

##### Intervention groups

Intervention group 1: Simultaneously with anesthesia, a bolus dose of dexmedetomidine and then infusion dose (1µg / kg and 0.5µg / kg / hr) will be administered. Intervention group 2: Simultaneously with anesthesia, a bolus dose of ketamine and then an infusion dose (0.25 mg / kg and 5 µg / kg / min) will be prescribed. Control group: will receive bolus dose and normal saline infusion dose.

##### Main outcome variables

Depth of anesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210415050976N5**

Registration date: **2021-06-22, 1400/04/01**

Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**

Update count: **0**

##### Registration date

2021-06-22, 1400/04/01

##### Registrant information

###### Name

navid kalani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5433 6085

###### Email address

k.navid@juma.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-01, 1400/06/10

##### Expected recruitment end date

2021-12-31, 1400/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Ketamine and Dexmedetomidine in Maintenance of Anesthesia with Bispectral Index Scale during General Anesthesia

##### Public title

Comparison of ketamine and dexmedetomidine in maintenance anesthesia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Being an NPO for 8 hours ASA class one or two  
Satisfaction with general anesthesia

### Exclusion criteria:

High blood pressure Severe cardiovascular disease  
Severe dysfunction of the liver and kidneys

## Age

From **20 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, block randomization method is used. With the help of the online site ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)) randomization, 8 blocks of 15 are created. In each block, randomly classified, 5 patients are assigned to the ketamine group, 5 patients to the dexmedetomidine group, and 5 patients to the control group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

For blinding, in the present study, the double-blind method is used so that the person reviewing the results and the person performing the injections do not know which patient received dexmethomedin and ketamine.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

##### Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University

of Medical Sciences, Vice Chancellor for Research

#### City

Jahrom

#### Province

Fars

#### Postal code

7167758256

#### Approval date

2019-10-09, 1398/07/17

#### Ethics committee reference number

IR.JUMS.REC.1398.045

## Health conditions studied

### 1

#### Description of health condition studied

General anesthesia

#### ICD-10 code

A21.7

#### ICD-10 code description

Generalized tularemia

## Primary outcomes

### 1

#### Description

Depth of anesthesia

#### Timepoint

After induction of anesthesia by an observer until the end of anesthesia will continue every 15 minutes.

#### Method of measurement

Cerebral State Monitor device made by Donmeter.dk company from Denmark and electrocardiographic electrodes will be used.

## Secondary outcomes

### 1

#### Description

The pain

#### Timepoint

After surgery in recovery

#### Method of measurement

Pain is assessed according to the ruler criteria.

### 2

#### Description

Frequent nausea and vomiting

#### Timepoint

In recovery

#### Method of measurement

Based on the frequency of nausea and vomiting

## Intervention groups

## 1

### Description

Intervention group 1: Dexmedetomidine infusion dose of 0.5 to 1 macro / kg body weight per hour will be administered during general anesthesia. The drug dexmedetomidine is used under the brand name Seddox, owned by Themis Medicare, and the vial of NDCC contains 200 micrograms of dexmedetomidine.

### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: Ketamine infusion dose of 25. Up to 0.5 macro / kg body weight per hour will be administered during general anesthesia. Ketamine used is made by Pfizer company in Germany and its ampoule contains 10 cc of 500mg solution.

### Category

Treatment - Drugs

## 3

### Description

Control group: Simultaneously with anesthesia, a bolus dose of distilled water will be given as a placebo.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Peymaniyeh Hospital of Jahrom city

#### Full name of responsible person

Navid Kalani

#### Street address

Jahrom, Shahid Motahari Boulevard, Peymanieh Hospital

#### City

Jahrom

#### Province

Fars

#### Postal code

71677251542

#### Phone

+98 71 3525 5652

#### Email

Navidkalani@ymail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Jahrom University of Medical Sciences

#### Full name of responsible person

Kavous Solh Joo

### Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

### City

Jahrom

### Province

Fars

### Postal code

7167758256

### Phone

+98 71 2536 5231

### Email

Navidkalani@ymail.com

### Web page address

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

#### Full name of responsible person

Navid Kalani

#### Position

Research Expert

#### Latest degree

Master

#### Other areas of specialty/work

Anesthesiology

#### Street address

Jahrom, Shahid Motahari Boulevard

#### City

Jahrom

#### Province

Fars

#### Postal code

7167758256

#### Phone

+98 71 2536 5231

#### Email

k.navid@jums.ac.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

**Street address**

Jahrom, Shahid Motahari Boulevard 7167758256

**City**

Jahrom

**Province**

Fars

**Postal code**

7167758256

**Phone**

+98 71 2536 5231

**Email**

k.navid@jums.ac.ir

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Master

### **Other areas of specialty/work**

Anesthesiology

### **Street address**

Jahrom, Shahid Motahari Boulevard

### **City**

Jahrom

### **Province**

Fars

### **Postal code**

7167758256

### **Phone**

+98 71 2536 5231

### **Email**

k.navid@jums.ac.ir

## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

### **Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

### **Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available