

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) 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous Solh Joo

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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

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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