Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

A comparison between intravenous ketamine and precedex (dexmedetomidine) in treatment of postoperative shivering after nose surgeries

Protocol summary

Study aim
Providing a more appropriate and effective drug with less complications for the treatment of postoperative shivering

Design
Randomised clinical trial with blocking of 4 and 2 parallel groups and phase 4 study on 88 patients in double blind form

Settings and conduct
Patients undergoing elective nasal surgery under general anesthesia at Kowsar hospital, who suffered from shivering during recovery, were randomly assigned to one of two treatment groups. To blind the study, the drugs are diluted in a volume of 2 ml and injected with syringes encrypted by a doctor who does not know the details of the treatment. Patients are not informed about the type of drug received; Both groups of patients are anesthetized in a similar way; Patients' chills grade are recorded before treatment begins. After receiving the drug, patients are followed for 10 minutes for the main outcome and other consequences and 30 minutes for complications.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients undergoing elective nasal surgery lasting 1-2 hours (including rhinoplasty, septoplasty, functional endoscopic sinus surgery, polyps and other intranasal masses), receiving general anesthesia, postoperative shivering, with ASA class one and two. Exclusion criteria: Patients with ASA class three or more, with a history of tremor, and Parkinson's disease, thyroid, heart, kidney, and liver diseases, anemia (hemoglobin less than 9), allergies, neurological and psychological diseases, myopathy, receiving blood during surgery, and the drug users

Intervention groups
1- Ketamine group: Receiving 0.3mg/kg/IV ketamine. 2- Precedex group: Receiving 1µg/kg/IV treatment of Precedex.

Main outcome variables
The main outcome is faster treatment of shivering in patients with shivering after anesthesia; Other consequences include body temperature, hemodynamic changes, and side effects from medication.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210728052003N1**
Registration date: **2021-09-08, 1400/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-08, 1400/06/17**
Update count: **0**

Registration date
2021-09-08, 1400/06/17

Registrant information

Name
Behzad Ahsan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3366 4645

Email address
behzad.ahsan@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between intravenous ketamine and precedex (dexmedetomidine) in treatment of postoperative shivering after nose surgeries

Public title

A comparison between ketamine and precedex in treatment of shivering

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective nasal surgery with a duration of 1-2 hours (including rhinoplasty, septoplasty, functional endoscopic sinus surgery, polyps, and other intranasal masses) Patients receiving general anesthesia Patients with shivering after surgery Patients with ASA class one and two

Exclusion criteria:

Patients with ASA class three and more Patients with a history of tremor and Parkinson's disease Patients with a history of thyroid, heart, kidney, and liver diseases, anemia (hemoglobin less than 9) Patients with a history of allergies Patients receiving blood during surgery Patients with a history of neurology and psychology diseases Patients with a history of myopathy Drug users

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups receiving ketamine and Precedex using the formation of 4 random blocks and random selection from these blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, the drugs are diluted in a volume of 2 ml and injected with syringes encrypted by a doctor who does not know the details of the treatment of patients. Patients are also not informed about the type of drug received.

Placebo

Not used

Assignment

Parallel

Other design features

ASA classification:1: A person with normal health without any systemic problems. 2: A person with mild systemic disease who has not had functional limitations. 3: A person with severe systemic disease who has functional limitations for the person. 4: A person who has a severe systemic disease and whose life is in danger. 5: A person who is dying and is not expected to survive surgery. 6: A person who has died of brain damage and is sent to the operating room to donate an organ; Both groups of patients are anesthetized in a similar way:Premedication:Fentanyl 1.5 µg / kg / IV, Midazolam 1mg / IV, Lidocaine 1mg / kg / IV, Dexamethasone 8 mg / IV. All patients receive the fluid they need to compensate for the NPO based on the anesthesia group policies. Induction of anesthesia: Propofol 1.5mg / kg / IV then Atracurium 0.5mg / kg / IV. Maintenance: Isoflurane 1.5% + N2O (3L) + O2 (3L).Reverse neuromuscular block at the end of surgery: Atropine 1.5 mg and Neostigmine 2.5 mg. All patients are tubed with a spiral tube and receive the fluid they need during the operation according to the policies of the anesthesia group. The operating room temperature in all patients is 27 degrees Celsius. Cover all patients during surgery and in Recovery is the same and blankets are used to warm them in recovery. For both groups of patients, gender, age, weight, height, duration of anesthesia and duration of surgery are recorded. Gender based on men and women; Age by year; Weight by scales; Height by meter; Duration of anesthesia in minutes; Duration of surgery in minutes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sanandaj University of Medical Sciences

Street address

Sanandaj University of Medical Sciences, Pasdaran Blvd., Sanandaj, Kurdistan Province

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2020-01-07, 1398/10/17

Ethics committee reference number

IR.MUK.REC.1398.310

Health conditions studied

1

Description of health condition studied
postoperative shivering
ICD-10 code
M61.50
ICD-10 code description
Other ossification of muscle, unspecified site

Primary outcomes

1

Description
The primary or main outcome of this study is faster treatment of shivering in patients with shivering after anesthesia. (Reduce patients' chills)
Timepoint
The degree of shivering in patients is determined and recorded before receiving the drug and from zero to 10 minutes every minute after receiving the drug.
Method of measurement
Postoperative shivering grading: Based on 5-digit grading (0 to 4) Grade 0: No shivering. Grade 1: Mild cold and chills on face or neck or one or more of the symptoms: Mild peripheral vasoconstriction, peripheral cyanosis, body hair spiking for no other reason. Grade 2: Moderate chills (involvement of one muscle group: oral muscle spasm) Grade 3: Severe chills (involvement of more than one muscle group without generalized involvement: spasm of all facial muscles) Grade 4: Generalized body chills

Secondary outcomes

1

Description
body temperatures
Timepoint
Patients' body temperature is recorded 5 times before induction of anesthesia, at the time of entering the recovery, before receiving the drug, 5 minutes after receiving the drug and 10 minutes after receiving the drug.
Method of measurement
It is measured from the axillary area by a thermometer.

2

Description
Hemodynamic changes
Timepoint
For both groups of patients, hemodynamic variables including HR, RR , SBP and DBP, SaO2 4 times before medication,1 minute after receiving the drug and 5 and 10 minutes after receiving the drug is recorded.
Method of measurement
HR (via distal pulse of the upper limb), RR (number of patient breaths per minute), SBP and DBP (via barometer), SaO2 (via pulse oximetry)

3

Description
Side effects from medications
Timepoint
Patients are monitored and recorded for drug side effects, including nausea and vomiting, tachycardia, hypertension, nystagmus, delirium, and other side effects up to 30 minutes after receiving the drug.
Method of measurement
Patients are evaluated after receiving the drug.

Intervention groups

1

Description
Intervention group: Ketamine group: They receives 0.3 mg / kg / IV treatment of ketamine.
Category
Treatment - Drugs

2

Description
Intervention group: Percedex receiving group: They receive 1 µg / kg / IV treatment of Percedex.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital, Sanandaj
Full name of responsible person
Behzad Ahsan
Street address
Kowsar Hospital, Mahvi Blvd., Pasdaran Blvd., Sanandaj, Kurdistan Province
City
Sanandaj
Province
Kurdistan
Postal code
6617983476
Phone
+98 87 3361 1232
Email
behzad.ahsan@muk.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Afshin Maleki
Street address
Sanandaj University of Medical Sciences, Pasdaran Blvd., Sanandaj, Kurdistan Province
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Phone
+98 87 3366 4645
Email
maleki43@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Behzad Ahsan
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Kowsar Hospital, Mahvi Blvd., Pasdaran Blvd., Sanandaj, Kurdistan Province
City
Sanandaj
Province
Kurdistan
Postal code
6617983476
Phone
+98 87 3361 1232
Email
behzad.ahsan@muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Behzad Ahsan
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Kowsar Hospital, Mahvi Blvd., Pasdaran Blvd., Sanandaj, Kurdistan Province
City
Sanandaj
Province
Kurdistan
Postal code
6617983476
Phone
+98 87 3361 1232
Email
behzad.ahsan@muk.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Sepideh Salehi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Education
Street address
Sanandaj University of Medical Sciences, Pasdaran Blvd., Sanandaj, Kurdistan Province
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Phone
+98 87 3366 4645
Email
sepideh.salehi.9595@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

Not applicable

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

Not applicable

Title and more details about the data/document

All data including proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years.

To whom data/document is available

All persons will access to the data upon request to the Research and Technology Dept. of Kurdistan Medical Science.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Sepideh Salehi Address: Sanandaj University of Medical Sciences, Pasdaran Blvd., Sanandaj, Kurdistan Province Postal code:6617713446 00989142567880 sepideh.salehi.9595@gmail.com Behzad Ahsan Address: Kowsar Hospital, Mahvi Blvd., Pasdaran Blvd., Sanandaj, Kurdistan Province Postal code:6617983476 00989181719003 behzad.ahsan@muk.ac.ir

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

After submitting a request to the Research and Technology Dept. of Kurdistan Medical Science , a call for submission is given.

Comments