

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

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+98 87 3366 4645

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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

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Province

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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 receive 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

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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

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

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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

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
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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