Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparative study of the effect of intravenous dexmedetomidine and remifentanil on cardiovascular response to extubation in awake patients undergoing surgery.

Protocol summary

Study aim

Determining and comparing the effect of intravenous dexmedetomidine and remifentanil on cardiovascular response to extubation in awake patients undergoing surgery

Design

A randomized, double-blinding clinical trial, with parallel groups, Phase 3 on 90 patients

Settings and conduct

In this randomized double-blind clinical trial study, 90 surgical candidates patients in Al-Zahra Hospital of Isfahan will be included in the study and will be randomly divided into three groups. After general anesthesia, remifentanil, dexmedetomidine and normal saline infusion will be prescribed in three groups, respectively. The intervention will be performed in such a way that the patient, the researcher will have no knowledge of the type of intervention. Then hemodynamic parameters, and complications after surgery will be evaluated.

Participants/Inclusion and exclusion criteria

The inclusion criteria include patients who are candidates for elective surgery, in the age range of 20-60 years, with ASA class equal to 1 or 2, weight 55 to 85 kg and consent to participate in the study. Exclusion criteria includes pregnancy, having comorbidity, having a heart rate< 60 bpm baseline time, or systolic blood pressure< 90 mmHg, having an allergy to the studies drugs and using drugs.

Intervention groups

First intervention group: Normal saline 70 cc will be prescribed within 10 minutes and remifentanil 0.3 microgram/kg in a volume of 3 cc one minute after extubation. The second intervention group: Dexmedetomidine 0.7 µg/kg in 70 ml of normal saline will be prescribed for 10 minutes and normal saline in a volume of 3 cc one minute after extubation. Control group: 70 ml of normal saline will be administered within 10 minutes and then 3 cc of normal saline will be administered one minute after extubation.

Main outcome variables

Blood pressure, heart rate, oxygen saturation(Spo2); Bradycardia; hypertension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N74**
Registration date: **2024-02-18, 1402/11/29**
Registration timing: **prospective**

Last update: **2024-02-18, 1402/11/29**
Update count: **0**

Registration date

2024-02-18, 1402/11/29

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of intravenous dexmedetomidine and remifentanil on cardiovascular response to extubation in awake patients undergoing surgery.

Public title
Effect of intravenous dexmedetomidine and remifentanil on cardiovascular response to extubation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for elective surgery under general anesthesia Age range from 20 to 60 years American Society of Anesthesiologists (ASA) class equal to 1 or 2 Weight 55 to 85 kg (body mass index 18.5-24.9 kg/m2) Consent to participate in the study
Exclusion criteria:
Pregnancy Having underlying diseases (including diabetes, chronic lung disease, cardiovascular disease, uncontrolled blood pressure, kidney failure) Having a heart rate of less than 60 beats/minute or a systolic blood pressure of less than 90 mmHg upon entering the study. Having an allergy to the drugs used Drug use
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Before starting the study, letter A is written on 30 sheets, letter B is written on 30 sheets, and letter C is written on 30 sheets, and each is placed in an envelope. Then, each eligible patient who consented to participate in the study is asked to choose an envelope from among the envelopes. In this way, the patient will be randomly assigned to one of the two groups according to the envelope selected without the interference of the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to achieve the double-blind study, different doses of remifentanil will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B and C. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2020-11-23, 1399/09/03
Ethics committee reference number
IR.MUI.MED.REC.1399.748

Health conditions studied

1

Description of health condition studied
Elective surgery
ICD-10 code
Y83.9
ICD-10 code description
Surgical procedure, unspecified as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
Before induction of anesthesia, before extubation, 1, 3, 5, and 10 minutes after extubation

Method of measurement
Monitoring device

2

Description
Diastolic blood pressure
Timepoint
Before induction of anesthesia, before extubation, 1, 3, 5, and 10 minutes after extubation
Method of measurement
Monitoring device

3

Description
Heart rate
Timepoint
Before induction of anesthesia, before extubation, 1, 3, 5, and 10 minutes after extubation
Method of measurement
Monitoring device

4

Description
Oxygen saturation (SPO2)
Timepoint
Before induction of anesthesia, before extubation, 1, 3, 5, and 10 minutes after extubation
Method of measurement
Monitoring device

Secondary outcomes

1

Description
Tachycardia
Timepoint
before induction of anesthesia, before extubation, 1, 3, 5, and 10 minutes after extubation
Method of measurement
Heart rate more than 100 beats per minute

2

Description
Bradycardia
Timepoint
before induction of anesthesia, before extubation, 1, 3, 5, and 10 minutes after extubation
Method of measurement
Heart rate less than 60 beats per minute

3

Description
Cough
Timepoint
After extubation
Method of measurement
Observation

4

Description
Laryngospasm
Timepoint
After extubation
Method of measurement
Observation

5

Description
Hypoxia
Timepoint
After extubation
Method of measurement
Oxygen less than 60 bpm

Intervention groups

1

Description
The first intervention group: Induction of anesthesia in patients with propofol (2 mg/kg), fentanyl 2 µg/kg and atracurium (0.5 mg/kg). Then, in this group, normal saline 70 cc will be prescribed within 10 minutes and remifentanil 0.3 microgram/kg in a volume of 3 cc one minute after extubation.
Category
Treatment - Drugs

2

Description
The second intervention group: Induction of anesthesia in patients with propofol (2 mg/kg), fentanyl 2 µg/kg and atracurium (0.5 mg/kg). Then, in this group, dexmedetomidine 0.7 µg/kg in 70 ml of normal saline will be prescribed for 10 minutes and normal saline in a volume of 3 cc one minute after extubation.
Category
Treatment - Drugs

3

Description
Control group: Induction of anesthesia in patients with propofol (2 mg/kg), fentanyl 2 µg/kg and atracurium (0.5 mg/kg). Then, in this group, 70 ml of normal saline will be administered within 10 minutes, and then 3 cc of normal saline will be administered one minute after extubation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Hamidreza Shetabi
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Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hamidreza Shetabi
Position
Associate Professor
Latest degree
Subspecialist
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Specialist
Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available