

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 remifentanyl on cardiovascular response to extubation in awake patients undergoing surgery.

Public title

Effect of intravenous dexmedetomidine and remifentanyl 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 remifentanyl 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

Isfahan

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 remifentanyl 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

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

hamid.shetabi@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

hamid.shetabi@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

hamid.shetabi@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Faezeh Poursajad

Position

Non-faculty specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh
Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Fax

Email

faezeh_p28@yahoo.com

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