Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of dexmedetomidine as a main anastasia drug with propofol on maintain sufficient depth of anesthesia in patients undergoing elective laparotomy

Protocol summary

Study aim
Comparison of dexmedetomidine as a main anastasia drug with propofol on maintain sufficient depth of anesthesia in patients undergoing elective laparotomy

Design
Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 30 patients. In order to randomize, the block randomization method will be used.

Settings and conduct
In this research, all patients who need elective laparotomy surgery, referring to Firuzgar Hospital, will be included in the study. Patients will be randomly divided into 2 groups based on blocks of 6. The sample size for each study group is 15 people. A total of 30 patients will be examined. Patients, surgeon and data analyst will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for elective laparotomy surgery; patients over 18 years. Exclusion criteria: Patients over 60 years; Emergency surgery; Contraindications to the use of dexmedetomidine; Pregnancy or breastfeeding; Drug addiction; Uncontrolled blood pressure; Body mass index above 30.

Intervention groups
Intervention group: In order to administer anesthesia during the procedure, dexmedetomidine infusion continues at a rate of 1 mcg/kg/hour, and the patient receives morphine 5 mg intravenously, and cis-atracurium infusion is started at a rate of 2 mcg/kg/minute. Control group: Propofol infusion is started at a dose of 50-100 mcg/kg/minute to administer anesthesia during the procedure. Patients receive 5 mg of intravenous morphine and the infusion of cis-atracurium is started at a dose of 2 mcg/kg/min.

Main outcome variables
Depth of anesthesia; Pain level of patients; Agitation score; Sedation score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151107024909N12**
Registration date: **2022-10-30, 1401/08/08**
Registration timing: **prospective**

Last update: **2022-10-30, 1401/08/08**
Update count: **0**

Registration date
2022-10-30, 1401/08/08

Registrant information

Name
Faranak Rokhtabnak

Name of organization / entity
Iran University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 21 8894 6267

Email address
rolhtabnak.f@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-06, 1401/08/15

Expected recruitment end date
2023-05-05, 1402/02/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dexmedetomidine as a main anastasia drug with propofol on maintain sufficient depth of anesthesia in patients undergoing elective laparotomy

Public title

Comparison of dexmedetomidine with propofol in maintaining adequate depth of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 20 years Patients who are candidates for laparotomy surgery Surgery with a time of more than 3 hours under general anesthesia

Exclusion criteria:

Patients over 60 years Emergency surgery Contraindications to the use of dexmedetomidine Pregnancy or breastfeeding Drug addiction Uncontrolled blood pressure Body mass index above 30

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups. The randomization tool will be a random sequence generation software called SAS. In addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 6 blocks will be formed and in each block, 3 people from intervention group and 3 people in control group 3 will be placed. A total of 5 blocks will be considered to reach the sample size. The blocks contain numbers, odd numbers represent the intervention group and even numbers represent the control group. Their order will be determined by the software initially. Random allocation concealment will be done using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. the door At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The surgeon and the patients will be blinded and unaware of the type of anesthesia. Similar serums were used for concealment, without drug name labels and only with a code. Patients will be aware that they will be randomly assigned to one of the two treatment groups but will not know which treatment will be provided in that group. The surgeon also knows that two different methods will anesthetize the patients, but he will not know which method will be used for each patient. The person in charge of data collection, the analyst, and the outcome evaluator will collect and analyze the data based on groups 1 and 2 and will not know the type of treatment provided in the groups and will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-04-23, 1401/02/03

Ethics committee reference number

IR.IUMS.FMD.REC.1401.079

Health conditions studied

1

Description of health condition studied

Anesthesia

ICD-10 code

Y48.4

ICD-10 code description

Anaesthetic, unspecified

Primary outcomes

1

Description

Depth of anesthesia

Timepoint

At the beginning and during surgery

Method of measurement

Anesthesia depth monitoring device

2

Description

Pain level of patients

Timepoint

From the beginning of recovery every 15 minutes up to three times

Method of measurement

Visual analog scale

3

Description

Agitation score

Timepoint

From the beginning of recovery every 15 minutes up to three times

Method of measurement

Based on the information in the patient's file

4

Description

Sedition score

Timepoint

From the beginning of recovery every 15 minutes up to three times

Method of measurement

Based on the information in the patient's file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Induction included midazolam 0.03 mg/kg (Manufacturing factory: Abu Rayhan), fentanyl 2 mg/kg (manufacturer: Norman SA), propofol 1-2 mg/kg (manufacturer: Bran B), cis-atracurium 0.2 mg/kg. kg (Manufacturing factory: Behin Tamin Roza Mod Co.) After reaching the necessary conditions for intubation, the patient is intubated with a suitable size tube. During this time, the dexmedetomidine infusion continues. In order to administer anesthesia during the procedure, the infusion of dexmedetomidine (manufacturer: Exir) continues at a rate of 1 mcg/kg/hr, and the patient receives 5 mg of morphine intravenously, and the infusion of cis-atracurium is started at the rate of 2 mcg/kg/min. If the depth of anesthesia increases more than 50, the amount of dexmedetocidin 0.25% is added and it can be added up to ten times the initial sedation dose to maintain the level of sedation at 40-50. If the depth of anesthesia decreases from 40 in this group, the dose of dexmedetomidine will be reduced until the depth of anesthesia reaches an acceptable level, and if there is no response to increasing the dose of propofol or complications, isoflurane gas (manufacturer: Piramal) will be used in the amount of 0.5%. As long as the depth of anesthesia can be maintained as necessary, the concentration of inhalation gas is increased.

Category

Treatment - Drugs

2

Description

Control group: Induction included midazolam 0.03 mg/kg (Manufacturing factory: Abu Rayhan), fentanyl 2 mg/kg (manufacturer: Norman SA), propofol 1-2 mg/kg (manufacturer: Bran B), cis-atracurium 0.2 mg/kg. kg (Manufacturing factory: Behin Tamin Roza Mod Co.) After reaching the necessary conditions for intubation, the patient is intubated with a suitable size tube. Normal saline infusion continues during this time. To administer anesthesia during the procedure, propofol infusion is started at a dose of 50-100 mcg/kg/min (Manufacturing factory: Shafa Farmed). Patients receive 5 mg of intravenous morphine and the infusion of Cis-atracurium starts with a dose of 2 mcg/kg/min. To keep the depth of anesthesia constant between 40-50, if the depth of anesthesia increases by 20%, the infusion of propofol will be increased. And if the depth of anesthesia falls below 40, the amount of propofol will be reduced by 20% and this will continue until the depth of anesthesia can be kept between 40 and 50 and the maximum dose of propofol (200 ug/kg) reached, and in case of failure to respond to propofol dose increase or side effects, 0.5% isoflurane gas (manufacturer: Piramal) will be used until the depth of anesthesia can be maintained at the required level, the inhalation gas concentration will be increased.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Faranak Rokhtabnak

Street address

Vali Asr Sq. Beh Afarin Ave.

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1600

Email
h_firoozgar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hossein Keyvani

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2503

Email
research@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Faranak Rokhtabnak

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Firouzgar hospital. Vali Asr Sq. Beh Afarin Ave.

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 6640 6761

Email
rolhtabnak.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Faranak Rokhtabnak

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Firouzgar hospital. Vali Asr Sq. Beh Afarin Ave.

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 6640 6761

Email
rolhtabnak.f@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Faranak Rokhtabnak

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Firouzgar hospital. Vali Asr Sq. Beh Afarin Ave.

City
Tehran

Province
Tehran

Postal code
1593747811
Phone
+98 21 6640 6761
Email
rolhtabnak.f@iums.ac.ir

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