

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of two anesthesia methods, sevoflurane fentanyl and propofol fentanyl, on the severity of cough and laryngospasm in orthopedic surgeries under one hour.

Protocol summary

Study aim

Reduction of complications and death caused by anesthetic drugs

Design

The clinical trial with double-blind, randomized phase 3 is on 148 patients. In this study, the samples are randomly selected with the help of a random number table.

Settings and conduct

The patients include 148 participants who are candidates for orthopedic surgery, referring to the orthopedic surgery department of Shahid Mohammadi Hospital, Prophet Azam complex, Bandar Abbas. The patients are under complete cardiac monitoring of oxygen saturation and blood pressure. First, pre-oxygenation with a mask and pre-medication with midazolam (2 mg), fentanyl (2 µg/kg) are performed. Anesthesia induction is performed with propofol (2 mg/kg) and atracurium (0.5 mg/kg). After 3 to minutes, ventilation is done with an LMA mask based on weight. and the variables of the study are measured at the end of the operation after extubation and upon entering the recovery room, after 15 minutes and half an hour after entering the recovery room, and one hour after entering the recovery room. The patients are unaware of the type of drug combination used for anesthesia. they will be. The anesthetist and the one collecting the data are different.

Participants/Inclusion and exclusion criteria

Entry criteria: age 18-75 years old. Exit criteria: not filling out the informed consent form; lack of necessary conditions to receive anesthetic such as heart and kidney diseases; instability of hemodynamic condition and drug abuse.

Intervention groups

In one group, propofol with a dose of 100 micrograms per kilogram of weight per minute and in the other group, sevoflurane with MAC = 2 is used for induction of anesthesia. Patients are under full monitoring of heart,

blood pressure and oxygen saturation evaluation.

Main outcome variables

Cough severity; laryngospasm; oxygen saturation level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231014059718N1**

Registration date: **2024-02-03, 1402/11/14**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-03, 1402/11/14**

Update count: **0**

Registration date

2024-02-03, 1402/11/14

Registrant information

Name

Mahsa Abednezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 76 3242 1819

Email address

mahsaabednejad95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two anesthesia methods, sevoflurane fentanyl and propofol fentanyl, on the severity of cough and laryngospasm in orthopedic surgeries under one hour.

Public title

Comparison of two anesthesia methods, sevoflurane fentanyl and propofol fentanyl, on the severity of cough and laryngospasm in orthopedic surgeries under one hour.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 75 Consent to participate in the study

Exclusion criteria:

Heart and kidney diseases Hemodynamic instability Drug abuse

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Generating random numbers from the table of random numbers: Considering that 148 patients are needed in this study, a number was chosen randomly in the table of random numbers and the two digits on the right side of it were taken into account. If these two digits were an even number, the patient was intervention group A, and if there is an individual, they will be assigned to control group B. For example, in the table of random numbers, the number 63 was chosen, since 63 is an odd number, so the first sample will be assigned to the control group. People are divided into two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In each of the groups, the desired drug is injected into the patient by an anesthesiologist, but the desired information for the research is recorded by an independent researcher who does not know the type of drug and the study group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hormozgan university of medical sciences

Street address

Shahid mo'shammadi hospital, Jomhori Eslami Blvd.

City

Bandarabbas

Province

Hormozgan

Postal code

7916613885

Approval date

2022-12-31, 1401/10/10

Ethics committee reference number

IR.HUMS.REC.1401.326

Health conditions studied**1****Description of health condition studied**

Respiratory system problem

ICD-10 code

J95.89

ICD-10 code description

Other postprocedural complications and disorders of respiratory system, not elsewhere classified

Primary outcomes**1****Description**

Severity of cough

Timepoint

During the operation and after casteob and fifteen minutes later and half an hour and an hour later

Method of measurement

Aldrete score

2**Description**

Laryngospasm

Timepoint

During the operation and after casteob and fifteen minutes later and half an hour and an hour later

Method of measurement

Aldrete score

3

Description

Oxygen saturation percentage of arterial blood

Timepoint

During the operation and after casteb and fifteen minutes later and half an hour and an hour later

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 100 mcg per kilogram of body weight will receive propofol for induction of anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group 2: will receive sevoflurane with MAC=2 for anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid mohammadi hospital

Full name of responsible person

Doctor Majid vatankhah

Street address

Shahid mohammadi hospitl street

City

Bandar Abbas

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7916613885

Phone

+98 933 961 1441

Email

hormozgan91@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Wali Alipour

Street address

Shahid Mohammadi hospital

City

Bandarabbas

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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

Research Vice President of Bandar Abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr Majid vatankhah

Position

Associate Professor of Bandar Abbas University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

Dr majid vatan khah

Position

Associate Professor of Bandar Abbas University of Medical Sciences

Latest degree

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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

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparison of two anesthesia methods, sevoflurane fentanyl and propofol fentanyl, on the severity of cough and laryngospasm in patients who return to the orthopedic surgery department for orthopedic surgery.

When the data will become available and for how long

Up to one year after the publication of the article

To whom data/document is available

Authors and officials of Bandar Abbas University of Medical Sciences

Under which criteria data/document could be used

For use in statistical work and larger studies

From where data/document is obtainable

first author

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

Send an email to the first author and request the use of the data

Comments