

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

The effect of fentanyl and sufentanil in combination with propofol on changes in heart rate and blood pressure after laryngoscopy and endotracheal intubation

Protocol summary

Study aim

Comparison of the effect of fentanyl and sufentanil in combination with propofol on changes in heart rate and blood pressure after laryngoscopy and endotracheal intubation

Design

A non-randomized double-blinding clinical trial with the control group with parallel groups

Settings and conduct

This non-randomized double-blind clinical trial is carried out at Feyz Hospital in Isfahan. In this study, 96 eligible patients will be admitted and randomly divided into 3 parallel groups. Then, for these three groups, induction of anesthesia was performed with "propofol alone", "fentanyl in combination with propofol" and "sufentanil in combination with propofol", respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age range between 18-65 years, American Society of Anesthesiologists (ASA) classification equal to I or II, general anesthesia candidates require endotracheal intubation. Exclusion criteria include having kidney, liver, heart, or lung failure, addiction, having an airway abnormality, and being allergic to the drugs being studied.

Intervention groups

Intervention group 1: In this group for patients, induction of anesthesia with fentanyl 3 µg/kg at the time of induction of anesthesia with lidocaine 1.5 mg/kg, propofol 2 mg/kg with atracurium 0.6 mg/kg is performed. Intervention group 2: In this group for patients, induction of anesthesia with sufentanil 0.3 µg / kg during induction of anesthesia with lidocaine 1.5 mg/kg, propofol 2 mg/kg with atracurium 0.6 mg/kg is performed. Control group: In this group for patients, induction of anesthesia with normal saline at the time of induction of anesthesia with lidocaine 1.5 mg/kg, propofol 2 mg/kg with atracurium 0.6 mg/kg is

performed.

Main outcome variables

Heart rate, Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N18**

Registration date: **2021-01-01, 1399/10/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-01, 1399/10/12**

Update count: **0**

Registration date

2021-01-01, 1399/10/12

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

2020-11-21, 1399/09/01

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fentanyl and sufentanil in combination with propofol on changes in heart rate and blood pressure after laryngoscopy and endotracheal intubation

Public title

The effect of fentanyl and sufentanil in combination with propofol on changes in heart rate and blood pressure after laryngoscopy and endotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range between 18-65 years, American Society of Anesthesiologists (ASA) classification equal to I or II
General anesthesia candidates require endotracheal intubation

Exclusion criteria:

Having kidney, liver, heart, or lung failure
Addiction
Having an airway abnormality
Being allergic to the drugs under study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

To blind the study, the drugs will be prepared by an anesthesiologist before the intervention. In terms of the amount of the drug, all drugs will be reached the same volume using distilled water. These syringes will be coded and placed in the operating room and delivered daily to the anesthesiologist, who will prescribe them without knowing the type of medication. Also, the patient, 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

2020-10-17, 1399/07/26

Ethics committee reference number

IR.MUI.MED.REC.1399.632

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

Patients under general anesthesia require endotracheal intubation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Heart beat

Timepoint

Immediately before, 1, 3, 5 and 10 minutes after laryngoscopy

Method of measurement

Monitoring device

2**Description**

Blood pressure

Timepoint

Immediately before, 1, 3, 5 and 10 minutes after laryngoscopy

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group for patients, induction of anesthesia with normal saline at the time of induction of anesthesia with lidocaine 1.5 mg/kg, propofol 2 mg/kg with atracurium 0.6 mg/kg is performed.

Category

Placebo

2

Description

Intervention group 1: In this group for patients, induction of anesthesia with fentanyl 3 µg/kg at the time of induction of anesthesia with lidocaine 1.5 mg/kg, propofol 2 mg/kg with atracurium 0.6 mg/kg is performed.

Category

Treatment - Drugs

3

Description

Intervention group 2: In this group for patients, induction of anesthesia with sufentanil 0.3 µg / kg during induction of anesthesia with lidocaine 1.5 mg/kg, propofol 2 mg/kg with atracurium 0.6 mg/kg is performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Azim Honarmand

Street address

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

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8174675731

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honarmand@med.mui.a.ir

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Azim Honarmand

Street address

Anesthesiology Department, Kashani Hospital, Kashani Street.

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8183983434

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

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

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahdieh Kazemi

Position

Non-faculty medicine

Latest degree

Medical doctor

Other areas of specialty/work

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Mahdieh906@gmail.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