Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

A comparative study of the effect of two doses of sufentanil continuous infusion on changes in heart rate and blood pressure after laryngoscopy and tracheal intubation.

Protocol summary

Study aim
Determining and comparing the effect of two-dose sufentanil continuous infusion on changes in heart rate and blood pressure after laryngoscopy and tracheal intubation.

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

Settings and conduct
In this three-blind randomized clinical trial study, 90 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into 3 groups. During induction of anesthesia, sufentanil with a dose of 0.1 µg/kg, 0.2 µg/kg, and normal saline will be prescribed in three groups, respectively. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention. Then the hemodynamic parameters of patients will be evaluated and compared among the three groups.

Participants/Inclusion and exclusion criteria
The criteria for inclusion in the study include the age group of 18 to 65 years, having an American Association of Anesthesiologists (ASA) I, and requiring tracheal intubation for general anesthesia. Exclusion criteria include having Comorbidity(such as heart failure, respiratory, liver, kidney failure, and airway malformations), and addiction.

Intervention groups
Intervention group 1: In this group, anesthesia is induced within 60 seconds using sodium thiopental 5 mg/kg, lidocaine 1.5 mg/kg, atracurium 0.6 mg/kg, and sufentanil with a dose of 0.1 µg/kg. The second intervention group: in this group, in addition to the drugs of the first group, sufentanil is infused at a dose of 0.2 µg/kg within 60 seconds. Control group: in this group, in addition to the drugs of the first group, normal saline is prescribed instead of sufentanil.

Main outcome variables
Systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation(Spo2)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N62**
Registration date: **2022-11-06, 1401/08/15**
Registration timing: **prospective**

Last update: **2022-11-06, 1401/08/15**
Update count: **0**

Registration date
2022-11-06, 1401/08/15

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of two doses of sufentanil continuous infusion on changes in heart rate and blood pressure after laryngoscopy and tracheal intubation.

Public title

The effect of continuous administration of two doses of sufentanil on changes in heart rate and blood pressure after laryngoscopy and tracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range from 18 to 65 years American Society of Anesthesiologists (ASA) I Requires tracheal intubation for general anesthesia Consent to participate in the study

Exclusion criteria:

Having heart failure Having a systolic blood pressure of less than 14 mmHg and diastolic blood pressure of 9 mmHg Having respiratory, liver, kidney failure Having airway malformations having an addiction

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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 three groups according to the envelope selected without the interference of the researcher.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to achieve the triple-blind study, different doses of sufentanil and placebo 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

2022-02-20, 1400/12/01

Ethics committee reference number

IR.MUI.MED.REC.1400.816

Health conditions studied

1

Description of health condition studied

Patients requiring tracheal intubation for general anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Baseline time, before laryngoscopy, 1, 3, 10 minutes after laryngoscopy

Method of measurement

Ventilation device

2

Description
Diastolic blood pressure
Timepoint
Baseline time, before laryngoscopy, 1, 3, 10 minutes after laryngoscopy
Method of measurement
Ventilation device

3

Description
Heart beat
Timepoint
Baseline time, before laryngoscopy, 1, 3, 10 minutes after laryngoscopy
Method of measurement
Ventilation device

4

Description
Oxygen saturation (SPO2)
Timepoint
Baseline time, before laryngoscopy, 1, 3, 10 minutes after laryngoscopy
Method of measurement
Ventilation device

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: In this group, anesthesia is induced within 60 seconds using sodium thiopental 5 mg/kg, lidocaine 1.5 mg/kg, atracurium 0.6 mg/kg, and sufentanil with a dose of 0.1 µg/kg.
Category
Treatment - Drugs

2

Description
The second intervention group: in this group, in addition to the drugs of the first group, sufentanil is infused at a dose of 0.2 µg/kg within 60 seconds.
Category
Treatment - Drugs

3

Description
Control group: In this group, in addition to the drugs of the first group, normal saline is prescribed instead of sufentanil.
Category
Placebo

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

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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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

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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