

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of two dose of sublingual Sufentanil on heart rate and blood pressure changes after laryngoscopy and endotracheal intubation

Protocol summary

Study aim

Determination of the effect of two dose of sublingual Sufentanil on heart rate and blood pressure changes after laryngoscopy and endotracheal intubation

Design

Randomized controlled three blinded clinical trial on 96 patients undergoing intubation. Patients were randomly divided into three groups with simple randomization by Random Allocation Software

Settings and conduct

A clinical trial on 96 patients who will refer to the operating room center of Al-Zahra Hospital in Isfahan in the years 2020-2021. Patients, the physician who will collect the data, and the statistician who will analyze the data will not be informed about the patient's study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA I or ASA II; Patients aged 18 to 65 years; Patients who were candidates for elective surgery under general anesthesia requiring tracheal intubation. Exclusion criteria: Patients with cardiac, hepatic and renal insufficiency; patients with drug addictions; patients with airway anomalies.

Intervention groups

First Intervention group receive sublingual Sufentanil 0.1 microgram per kilogram 3 minutes before anesthetic drug injection. Second Intervention group receive sublingual Sufentanil 0.2 microgram per kilogram 3 minutes before anesthetic drug injection. Control group receive sublingual normal saline before anesthetic drug injection.

Main outcome variables

Systolic, diastolic and mean blood pressure; arterial oxygen saturation; mean heart rate; ST-T changes in electrocardiogram

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090129001615N5**

Registration date: **2020-11-26, 1399/09/06**

Registration timing: **retrospective**

Last update: **2020-11-26, 1399/09/06**

Update count: **0**

Registration date

2020-11-26, 1399/09/06

Registrant information

Name

Azim Honarmand

Name of organization / entity

Alzahra hospital

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

honarmand@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of two dose of sublingual Sufentanil on heart rate and blood pressure changes after laryngoscopy and endotracheal intubation

Public title
Evaluation of sublingual sufentanil effect in laryngoscopy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
age: 18-65 Patients with grade 1 or 2 of American Society of Anesthesiologists (ASA) grading patient needed endotracheal intubation in general anesthesia
Exclusion criteria:
Patients with heart failure disease Patients with renal failure disease Patients with hepatic failure disease Patients with airway anomalies Patients aged 18 to 65 years Patients with addiction to drugs

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: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by using SPSS software. We have 96 patients and we give them numbers from 1 to 96. Then we enter these numbers into the SPSS. This software divides the patients into three groups and each patient is assigned a specific random number. By these numbers each patient is in his own group. The unit of randomization is individualized.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The physician who will collect the patient's data and the statistician who will analyze data have no information about the study group assignments. The study drugs will be injected by similar syringes in volume and color and they also will be administered for patients after induction of anesthesia so the patients will have no information about the injected drugs

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

Isfahan university of medical science, Hezarjarib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.MUI.MED.REC.1399.421

Health conditions studied

1

Description of health condition studied

Patients who need generalize anesthesia with tracheal intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before intervention and 1, 3, 5 and 10 minutes after intervention

Method of measurement

Blood pressure manometer

2

Description

Diastolic blood pressure

Timepoint

Before intervention and 1, 3, 5 and 10 minutes after intervention

Method of measurement

Blood pressure manometer

3

Description

Heart rate

Timepoint

Before intervention and 1, 3, 5 and 10 minutes after intervention
Method of measurement
Heart monitoring

Secondary outcomes

1

Description

Arterial O2 saturation

Timepoint

Before intervention and 1, 3, 5 and 10 minutes after intervention

Method of measurement

Puls oximeter

2

Description

ST interval and T wave changes

Timepoint

Before intervention and 1, 3, 5 and 10 minutes after intervention

Method of measurement

Electrocardiogram

Intervention groups

1

Description

First intervention group receive sublingual Sufentanil 0.1 microgram per kilogram 3 minutes before anesthetic drug injection.

Category

Prevention

2

Description

Second Intervention group receive sublingual Sufentanil 0.2 microgram per kilogram 3 minutes before anesthetic drug injection.

Category

Prevention

3

Description

Control group receive sublingual normal saline before anesthetic drug injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Shokouh Sadeghizade Dehkordi

Street address

Alzahra hospital, Shohada sofe Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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 Honarman

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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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

No more information

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Main outcome information

When the data will become available and for how long

Since Publication

To whom data/document is available

Researchers working in academic, scientific and industrial institutes

Under which criteria data/document could be used

En Statistical analysis

From where data/document is obtainable

Dr Azim Honarmand

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

Send email and mention why you need documentation.

One to two weeks after sending the request

Comments