

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of intravenous fentanyl with and without topical lidocaine on hemodynamic responses to tracheal intubation; a double-blinded clinical trial

Protocol summary

Study aim

Comparison of intravenous fentanyl with and without topical lidocaine on hemodynamic responses to tracheal intubation

Design

A clinical trial with parallel, double-blind, randomized by randomizer website, phase 3 was performed on 100 patients in the two equal groups.

Settings and conduct

Phase 3 clinical trial with parallel groups was performed on 100 patients referred to Imam Khomeini hospital in Urmia. The first group received only 2µg / kg intravenous fentanyl and the second group received 2µg / kg intravenous fentanyl and 10 puffs of 10% lidocaine spray (equivalent to 100 mg) for oropharyngeal and epiglottal anesthesia. In this study, patients and clinical assessor as well as statistical analyzers were unaware of group assignment. Randomization was done by randomizer website.

Participants/Inclusion and exclusion criteria

Inclusion criteria were: age over 20 years and under 60 years; American Society of Anesthesiologists (ASA) I and II; patients who are candidates for elective surgery under general anesthesia and endotracheal intubation with cuffed tube. Exclusion criteria were: Morbid obesity (BMI above 40); history of any disease or abnormality that adversely affects anesthesia and surgery; history of any drug use that adversely affects anesthesia and surgery

Intervention groups

The first group received only 2µg / kg intravenous fentanyl and the second group received 2µg / kg intravenous fentanyl and 10 puffs of 10% lidocaine spray (equivalent to 100 mg) for oropharyngeal and epiglottal anesthesia.

Main outcome variables

Heart rate, systolic and diastolic blood pressure and mean arterial pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N3**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **retrospective**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Hadi Houshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3346 9931

Email address

hooshyar.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-26, 1398/04/05

Expected recruitment end date

2019-11-30, 1398/09/09

Actual recruitment start date

2019-07-07, 1398/04/16

Actual recruitment end date

2020-05-22, 1399/03/02

Trial completion date

2020-05-22, 1399/03/02

Scientific title

Comparison of intravenous fentanyl with and without topical lidocaine on hemodynamic responses to tracheal intubation; a double-blinded clinical trial

Public title

Effect of fentanyl with and without topical lidocaine on hemodynamic responses to tracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 20 years and under 60 years American Society of Anesthesiologists (ASA) I and II patients who are candidates for elective surgery under general anesthesia and endotracheal intubation with cuffed tube

Exclusion criteria:

Morbid obesity (BMI above 40) History of any disease or abnormality that adversely affects anesthesia and surgery History of any drug use that adversely affects anesthesia and surgery

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

At www.random.org website, in the "Enter List Items" section, the names of the study groups were written in equal numbers. That is, 50 number of "fentanyl with topical lidocaine group" and 50 number of "fentanyl without topical lidocaine group". Then the "Randomize" option was clicked. In this case, a list was presented that randomly and in different order had an equal number of groups and the patients were entered to the study in order of referral.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were unaware of their allocation into the intervention groups and the statistical analyzer received the data as codes, not the actual grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat Street, Jihad Ave., Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.UMSU.REC.1398.086

Health conditions studied

1

Description of health condition studied

Hemodynamic response to endotracheal intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate

Timepoint

Before intubation, immediately after intubation, 1, 3 and 5 minutes after intubation

Method of measurement

Pulsoximeter

2

Description

Systolic blood pressure

Timepoint

Before intubation, immediately after intubation, 1, 3 and 5 minutes after intubation

Method of measurement

Cardiovascular monitoring device

3

Description

Diastolic blood pressure

Timepoint

Before intubation, immediately after intubation, 1, 3 and 5 minutes after intubation

Method of measurement

Cardiovascular monitoring device

4

Description

Mean atrial pressure

Timepoint

Before intubation, immediately after intubation, 1, 3 and 5 minutes after intubation

Method of measurement

Cardiovascular monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group received 2µg / kg intravenous fentanyl (Caspian product) and 10 puffs of lidocaine spray 10% (equivalent to 100 mg) (Iran Daru product) about one minute before endotracheal intubation for oropharyngeal and epiglottal anesthesia

Category

Treatment - Drugs

2

Description

Intervention group: The second group just received only 2µg / kg intravenous fentanyl (Caspian product) about one minute before endotracheal intubation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital Urmia

Full name of responsible person

Hadi Hoshyar

Street address

Imam Khomeini hospital , Erash blvd , Urmia

City

Urmia

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West Azarbaijan

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57157-81351

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hooshyar.h@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

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mohebbi.i@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hadi Hooshyar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Motahhari Hospital; Kashani street; Urmia; Iran.

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is 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

Patients data will be shared based on codes assigned to patients

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Faculty Members

Under which criteria data/document could be used

Just research

From where data/document is obtainable

Email to Dr.Hoshyar

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

One week after sending the email and checking the purpose of the request

Comments