Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone
+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 lidocainegroup" and 50 number of "fentanyl without topical lidocainegroup". Then the "Ranomize" 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, Jahad 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
Province
West Azarbaijan
Postal code
57157-81351
Phone
+98 44 3346 9931
Email
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.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 1930
Email
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.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3198 8293

Email
hooshyar.h@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Hadi Hooshyar
Position
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Email
hooshyar.h@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Hadi Hooshyar
Position
Assistant professor
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hooshyar.h@umsu.ac.ir

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